

Medical Services Advisory Committee (MSAC) Public Summary Document

Application 1758 – Expansion of MBS item numbers 12320 & 12322 for bone mineral density (BMD) testing to include patients aged 60-69 years

Applicant: Department of Health and Aged Care

Date of MSAC consideration: 1-2 August 2024

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

1. Purpose of application

The Medical Services Advisory Committee (MSAC) Executive requested the Department of Health and Aged Care (the department) undertake a fit-for-purpose assessment of bone mineral density (BMD) testing in individuals aged 60 to 69 years. The aim of the report is to assess the economic and financial implications associated with amending the current age restriction for Medicare Benefits Schedule (MBS) items 12320 and 12322 from age 70 years and above to age 60 years and above, to align with proposals to amend the age restriction for Pharmaceutical Benefits Scheme (PBS) listed osteoporosis medicines for primary prevention of fractures.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost, MSAC did not support amending MBS items 12320 & 12322 for BMD testing to include all individuals aged 60-69 years. MSAC considered the proposed expansion to BMD testing, and all alternative scenarios, such as narrowing the expanded use to individuals aged 65-69 years without repeat testing, was not cost-effective. Additionally, MSAC noted the significant cost to the MBS across all modelled scenarios. MSAC was also concerned that the estimated utilisation and therefore budget impact may be underestimated based on the observation that there has been a significant increase in the utilisation of existing BMD services on the MBS. MSAC acknowledged the importance of osteoporosis prevention, diagnosis and management in high-risk groups. However, MSAC noted that access to BMD (dual-energy X-ray absorptiometry [DEXA] only) services on the MBS is already available to certain individuals within the proposed population such as those with minimal trauma fracture or other conditions associated with more rapid bone loss, and monitoring of patients on therapy.

MSAC advised the Department of Health and Aged Care to consider a broader review of BMD testing items, reflective of contemporary clinical guidelines, in particular for high-risk population groups such as First Nations people (who have a higher risk of fractures than non-First Nations people).

Consumer summary
This application from the Department of Health and Aged Care (the department) assessed the economic and financial implications of amending the age restriction for accessing bone mineral density testing under Medicare Benefits Schedule (MBS) items 12320 and 12322. Currently, these MBS items are for people aged 70 years or over. The application proposed to lower the eligible age to 60 years or over to align with proposed changes to the age restriction

Consumer summary

for Pharmaceutical Benefits Scheme (PBS)-listed osteoporosis medicines. There are other MBS items for bone mineral density testing. These are available for people who have had a bone break from a very minor accident or impact that wouldn't normally cause a fracture in a healthy bone (called minimal trauma fracture) or who have other conditions associated with more rapid bone loss, and monitoring of patients on therapy. These other MBS items for bone mineral density testing are not restricted by an individual's age and therefore, were not part for this application.

Osteoporosis is a condition in which the bones become fragile and brittle, leading to a higher risk of fractures (breaks or cracks). Fractures due to osteoporosis can lead to changes in posture, muscle weakness, loss of height and bone deformity of the spine. Fractures due to osteoporosis can also lead to acute and chronic pain, disability, loss of mobility and independence and early death. Diagnosis of osteoporosis requires an assessment of bone mineral density. There are different ways of assessing bone mineral density, including using dual-energy X-ray absorptiometry (DEXA scan) and quantitative computed tomography (QCT scan). If a bone mineral density test confirms that a person has osteoporosis, they may be eligible for osteoporosis medications listed on the PBS to prevent fractures.

MSAC noted that the Pharmaceutical Benefits Advisory Committee (PBAC) had previously considered proposals to expand the age restriction for PBS-listed osteoporosis medicines for prevention of fractures to include people aged 60–69 years. MSAC noted that the PBAC deferred making a recommendation, pending a review by MSAC of the MBS implications, to ensure that the bone densitometry MBS items could be aligned¹. This was because earlier access to the medications would require earlier and additional bone mineral density testing but the consequential economic and financial implications of this had not been reviewed.

MSAC noted that when the costs of bone mineral density testing were included, along with the costs and benefits of the osteoporosis medicines, lowering the age restriction to 60 years or over was not cost-effective. MSAC noted that the assessment presented alternative scenarios such as changing the age restriction to 65 years (instead of 60), and different re-testing frequencies (no retesting, every 2 years or every 5 years). However, MSAC noted that bone mineral density testing did not provide value for money in any of these alternative scenarios. MSAC also noted that, when the PBAC reviewed the updated economic analysis, the PBAC also concluded that expanding the restrictions for osteoporosis therapies to individuals aged 60-69 years was not cost-effective².

MSAC also noted that if bone mineral density testing was expanded to include people aged 60 years or over, the estimated total cost to the MBS was very high. MSAC was also concerned that the total cost to the MBS may be underestimated. MSAC noted that bone mineral density testing using the existing MBS items is one of the fastest-growing areas of the MBS and there are business models promoting bone mineral density testing.

MSAC acknowledged that it was beneficial to identify people at risk of osteoporosis and osteopenia at an earlier age. However, MSAC noted that certain individuals within the proposed population can already access other MBS items for bone mineral density testing (that were not part of this application). Further, clinical guidelines do not recommend using bone mineral density tests as a general screening tool for everyone. Rather they recommend

¹ Osteoporosis Therapy Restrictions Review, September 2021, PBAC meeting - <https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2021-09/September-2021-pbac-web-outcomes.pdf>

² Osteoporosis Therapy Restrictions Review, July 2024, PBAC meeting - <https://m.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2024-07/pbac-web-outcomes-07-2024.pdf>

Consumer summary

that doctors follow a decision-making flow chart to consider on a case-by-case basis whether the results of a bone mineral density test are needed to diagnose osteoporosis, provide personalised advice or prescribe an osteoporosis treatment for the individual patient. MSAC advised the department to consider reviewing all bone mineral density testing items to consider if the items are reflective of clinical guidelines, in particular the ability to access bone mineral density testing for diagnosis and monitoring of osteoporosis in high-risk population groups such as First Nations people (who have a higher risk of fractures than non-First Nations people).

MSAC's advice to the Commonwealth Minister for Health and Aged Care

MSAC did not support amending the age restriction (to include individuals aged 60-69 years) for accessing bone mineral density testing under MBS items 12320 and 12322. MSAC considered the proposed amendments would not provide value for money, would result in a significant increased cost to the MBS and that the true extent of this increased cost was very uncertain. MSAC considered the existing MBS items for bone mineral density testing could be reviewed to consider if they are reflective of current clinical guidelines.

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

MSAC noted that the MSAC Executive requested this fit-for-purpose assessment on the economic and financial implications of amending the age restriction for accessing BMD testing under MBS items 12320 and 12322. The proposal to amend the age restriction from ≥ 70 years of age to ≥ 60 years of age (for MBS items 12320 and 12322) was to align with proposals to amend the age restriction for PBS-listed osteoporosis medicines for primary prevention of fractures.

MSAC noted that consultation feedback provided mixed support for the application. The Royal Australian College of General Practitioners (RACGP) did not support the application and referred to their 2024 guidelines³ for Osteoporosis management which does not recommend population-based systematic screening with BMD measurement for reduction of osteoporotic fractures. Rather the RACGP guidelines recommend conducting risk factor assessment first (such as using the Fracture Risk Assessment Tool, FRAX) to then guide whether a BMD test and/or treatment should be considered. MSAC also noted that consultation feedback had commented on radiation exposure, that DEXA had less radiation exposure than quantitative computed tomography (QCT) but radiation dose is cumulative. The feedback considered DEXA preferable over QCT but that the additional radiation exposure and risk/benefit of DEXA versus QCT should be evaluated. MSAC agreed with the consultation feedback regarding radiation concerns with QCT and that radiation exposure (cumulation) should be considered but noted it is low with DEXA.

MSAC noted that the Pharmaceutical Benefits Advisory Committee (PBAC) had previously considered proposals to amend the age restriction for PBS-listed osteoporosis medicines to include individuals aged 60–69 years and who met the BMD criteria.^{4,5} On those occasions, the

³ <https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/osteoporosis/executive-summary>

⁴ PBAC outcome for Osteoporosis Therapy Restrictions Review, September 2021 PBAC meeting - <https://m.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2021-09/September-2021-pbac-web-outcomes.pdf>

⁵ Public Summary Document for risedronic acid, November 2022 PBAC meeting with March 2023 Addendum - <https://m.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2022-11/files/risedronic-acid-psd-11-2022-03-2023.pdf>

PBAC was of a mind to support lowering the age restriction but deferred consideration pending a review of the MBS implications, to ensure that the bone densitometry MBS items could be aligned with the PBAC recommendations.

MSAC also noted that PBAC had raised concern regarding optimistic assumptions that had been included in the economic evaluation for risedronate. MSAC noted that the economic evaluation for this application was based on the economic model for risedronate but that the model had been revised to address the concerns raised by PBAC, providing a more reliable model with assumptions that better reflected clinical practice. The results of this economic evaluation indicated the incremental cost per additional patient diagnosed with osteoporosis was \$4,673. MSAC also noted that PBAC had reviewed the updated economic evaluation at its July 2024 meeting and advised that the incremental cost-effectiveness ratio (ICER) per quality adjusted life year (QALY) gained from early initiation of osteoporosis treatment (detected via BMD testing) was not cost-effective (see July 2024 PBAC Outcomes⁶). MSAC noted that multiple sensitivity analyses exploring different age restriction (65–69 years) and reduced frequency or removal of repeat testing produced lower ICERs (see Tables 12, 13, 14, 15 and 16 in Section 10) but that the ICERs remained very high and of a magnitude that was not cost-effective.

MSAC noted that the financial analysis estimated that, if BMD testing was expanded to include individuals aged 60-69 years, the cumulative cost to the MBS over 6 years would be approximately \$134 million (base case). Sensitivity analyses indicated that the estimated financial impact was most sensitive to the uptake rate of BMD testing over time and the age band eligible for testing. MSAC noted the financial impact to the MBS would be lower if BMD testing was only expanded to include individuals aged 65–69 years without repeat testing (Table 19). MSAC considered that it can take 5 years for changes in BMD to be visible on DEXA scans. Therefore, MSAC considered it was reasonable to exclude repeat testing in the scenario exploring expanding BMD testing to individuals aged 65-69 years. However, MSAC noted that the estimated utilisation, for the base case and all scenario analyses, were uncertain due to a lack of data on BMD screening in individuals under 70 years of age not covered by Medicare. Further, recent MBS utilisation data demonstrated that utilisation of existing BMD testing items is one of the fastest-growing areas of the MBS. MSAC also noted there are business models that promote BMD screening. Therefore, MSAC considered the estimated utilisation (and therefore total costs to the MBS) were highly uncertain and likely underestimated in all scenarios.

Overall, MSAC did not support lowering the age restriction for BMD testing under MBS items 12320 and 12322 from ≥ 70 years of age to ≥ 60 years of age, or for any other scenarios presented. MSAC considered that the lowering the age restriction for MBS items 12320 and 12322 was not cost-effective and the estimated financial impact was uncertain and likely underestimated.

MSAC noted the suggestion from the Joint PBAC and MSAC ESCs to considered targeting the expansion of BMD testing to high-risk subpopulations within the 65-69 years age band, identified using the FRAX tool (i.e. those with a major osteoporotic fracture risk of $\geq 10\%$) and First Nations people (who have a higher risk of fractures than non-First Nations people), without repeat testing (see Section 13.). MSAC noted the PBAC and MSAC ESCs considered that targeting these high-risk subpopulations may improve the cost-effectiveness based on the assumption that the number needed to test (to identify an individual with osteoporosis) and treat (to prevent any fracture) would be reduced, and may have a more modest budget impact. However, MSAC noted the cost-effectiveness and financial impact for these high-risk subpopulations was not modelled and that there may be multiple data gaps that would limit the ability to adequately populate the economic evaluation and financial analysis for the high-risk subpopulations. MSAC noted that the department could consider submitting a proposal to the Medical Research Future Fund (MRFF) to

⁶ Osteoporosis Therapy Restrictions Review, July 2024, PBAC meeting - <https://m.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2024-07/pbac-web-outcomes-07-2024.pdf>

obtain the missing data that could enable an evaluation for expanding BMD testing to high-risk subpopulations suggested by the PBAC and MSAC ESCs.

MSAC noted that the existing MBS items for BMD testing do not appear to be reflective of the updated RACGP guidelines and that BMD testing not only supports diagnosis for accessing osteoporosis medications but also facilitates access to alternative therapies (such as physiotherapy and dietician support). MSAC noted there are other MBS items for BMD testing which are available for individuals with minimal trauma fractures (fractures that occur with little or no cause) or other conditions associated with more rapid bone loss, and monitoring of patients on therapy. These items are not restricted by an individual's age and were not in scope for this application. MSAC noted that while certain individuals within the proposed population may be able to access these other BMD items, MSAC advised the department to consider a broader review of BMD testing items, to consider whether they are reflective of contemporary clinical guidelines, in particular for high-risk population groups such as First Nations people.

4. Background

MSAC has previously considered multiple items related to BMD testing.

In November 2014, MSAC considered an application requesting MBS listing of bone densitometry by DEXA for all women in their 50th year of age (Public Summary Document [PSD] for MSAC Application 1162 – Bone Mineral Density analyses using DEXA for women in their 50th year). MSAC did not support public funding as there was no demonstrated advantage of DEXA over other methods of fracture risk assessment such as the FRAX online assessment tool; and Medicare benefits are not payable in respect of a health screening service.

In November 2014, MSAC also considered an application requesting MBS listing of bone densitometry by DEXA for postmenopausal women with early-stage breast cancer who receive, or are being considered for, treatment with aromatase inhibitors (PSD for MSAC Application 1313 – Bone Mineral Density analyses using DEXA in breast cancer patients receiving aromatase inhibitor treatment). MSAC deferred the application and requested further external evaluation of the economic modelling. The evidence was reconsidered at the July 2015 MSAC meeting. MSAC did not support public funding because of uncertain and unacceptably high cost-effectiveness in the proposed setting.

Between 2015 and 2020, the MBS Review Taskforce looked at more than 5,700 MBS items to see if they needed to be amended, updated or removed. At the time, seven MBS items for bone densitometry were identified for review by the Bone Densitometry Working Group (items 12306, 12309, 12312, 12315, 12318, 12321, 12323) (Medicare Benefits Schedule Review Taskforce, Second report from the Diagnostic Imaging Clinical Committee – Bone Densitometry, August 2016)⁷. Following the review, two time-restricted MBS items were introduced for BMD testing for people aged 70 years and above (items 12320 and 12322) to replace the existing MBS item that was not time-restricted (item 12323). Individuals aged 70 years or over would continue to be eligible for an initial test using item 12320. Individuals with a BMD T-score of -1.5 or above would be eligible for repeat testing every five years; and individuals with a BMD T-score less than -1.5 and above -2.5 would be eligible for repeat testing every two years. These changes were based on a review of international recommendations at the time as well as published research papers assessing the optimal timing of BMD testing (Frost 2009, Gourlay 2012).

In July 2022, MSAC considered an application requesting listing of ultrasound radiofrequency echographic multi spectrometry (REMS) for the diagnosis of osteopenia and osteoporosis (PSD for MSAC Application 1665 – Radiofrequency echographic multi spectrometry for bone density measurement and determination of osteopenia/osteoporosis). MSAC did not support public

⁷ <https://www.health.gov.au/resources/publications/final-clinical-committee-report-for-diagnostic-imaging-bone-densitometry?language=en>

funding as the evidence presented did not demonstrate sufficient correlation of REMS with DEXA. As such, MSAC queried whether there is a population for whom there is residual clinical need for REMS and suggested that re-application could instead identify those defined as eligible for DEXA but are unable to be tested by DEXA. MSAC also requested data on inter-machine variability, inter-operator variability and intra-patient variability over time.

Currently, unconditional access to bone densitometry (DEXA/QCT) is available to people aged 70 years and above, at specified time intervals (items 12320 and 12322). Conditional access to bone densitometry (DEXA only) is also available for patients with minimal trauma fracture (item 12306), conditions associated with more rapid bone loss (items 12312 and 12315) and monitoring of patients on therapy (item 12321).

In December 2022, the MSAC Executive noted the Pharmaceutical Benefits Advisory Committee (PBAC) considerations to expand the current age restriction for PBS listed osteoporosis medications for primary prevention of fractures to include individuals aged 60 to 69 years (see PBAC outcome for Osteoporosis Therapy Restrictions Review, September 2021 PBAC meeting and PSD for risedronic acid, November 2022 PBAC meeting with March 2023 Addendum). The PBAC deferred making a recommendation to amend the restriction, pending a review of the MBS implications, to ensure that the MBS items for bone densitometry could be aligned with the PBAC recommendations.

Redacted.

The MSAC Executive considered that bone densitometry for people aged 60 to 69 years should undergo an expedited assessment pathway that includes consideration by the Evaluation Sub-Committee (ESC) and MSAC to accurately capture the proposed net cost to the MBS as a result of expanding the population. The MSAC Executive advised that PICO Confirmation Advisory Sub-Committee (PASC) consideration was not needed as the Population Intervention Comparator and Outcomes (PICO) elements were well defined. The MSAC Executive considered that the MSAC assessment could focus on the high fracture risk population aged 60-69 years but noted that this would restrict access to testing for the full population considered by PBAC.

The MSAC Executive considered the assessment report should include an economic evaluation of BMD testing to determine eligibility for treatment (including repeat testing). The MSAC Executive advised that this could be incorporated into the existing risedronate economic model considered by the PBAC or a cost-consequence analysis. The MSAC Executive advised the assessment report should include net financial implications for the MBS. The MSAC Executive considered the assessment report should investigate the uptake of testing in practice as it may differ between males and females.

In February 2024, the MSAC Evaluation Sub-committee (ESC) considered the department contracted assessment report (DCAR) for application 1758. To address some outstanding uncertainties, the MSAC ESC requested additional work for the assessment to subsequently be jointly considered by the PBAC Economics Sub Committee (ESC)/MSAC ESC. This additional work was completed through the Addendum to the DCAR, included in Section 10 (Economic Evaluation) and Section 11 (Financial impacts) of this document below. In brief, the Addendum sought to provide a summary table of incremental cost-effectiveness ratios (ICERs) and budget impact analyses to inform MSAC advice on expanding MBS items 13230 and 12322, and the PBAC's reconsideration of its deferred advice from the Osteoporosis Therapy Restrictions Review in September 2021. The MSAC ESC also requested the department provide further information on the ICERs and financial estimates that informed past MSAC advice for Applications 1162, 1313, and 1665 as a potential frame of reference for MSAC consideration. This has been summarised below in Table 1 below.

Table 1 Comparison of key parameters of BMD testing applications to MSAC

	Application 1162	Application 1313	Application 1665	Application 1758								
MSAC consideration(s)	Nov 2014 : Not supported.	Nov 2014 : Deferred July 2015 : Not supported	July 2022 : Not supported	Aug 2024								
Population/Intervention	BMD testing (using DEXA scanning) for menopausal women aged 50	BMD using DEXA in breast cancer patients receiving aromatase inhibitor treatment	Patients who require a BMD measurement using REMS for the diagnosis or monitoring of osteoporosis and who are currently eligible for an MBS DEXA scan.	BMD testing (DXA or QCT) in 60-69 years								
Comparator	Clinical risk assessment without DEXA, including use of risk assessment	Clinical assessment including use of existing fracture risk assessment tools, vitamin D testing, with lifestyle and dietary advice.	DEXA	Standard care (i.e., no testing and standard medical management)								
Economic model	No economic evaluation presented as there is no demonstrated advantage of DEXA over other methods of risk assessment [PSD, p8]	CUA, 60 year cohort, lifetime.	Costing study- fee justification of delivery of REMS [PSD, p31]	Two-part analysis: Part A CEA universal BMD testing versus no BMD testing in individuals aged 60–69 years Parts A & B CUA of early vs delayed osteoporosis treatments#								
ICER/QALY	NA	<p>Previous base case-</p> <table border="1"> <tr> <td>DEXA + ARtx (osteoporosis)</td> <td>\$4,264</td> </tr> <tr> <td>DEXA + ARtx (osteoporosis + osteopenia)</td> <td>\$20,507</td> </tr> </table> <p>Revised base case- July 2015</p> <table border="1"> <tr> <td>DEXA + ARtx (osteoporosis)</td> <td>\$47,556</td> </tr> <tr> <td>DEXA + ARtx (osteoporosis + osteopenia)</td> <td>\$253,000</td> </tr> </table>	DEXA + ARtx (osteoporosis)	\$4,264	DEXA + ARtx (osteoporosis + osteopenia)	\$20,507	DEXA + ARtx (osteoporosis)	\$47,556	DEXA + ARtx (osteoporosis + osteopenia)	\$253,000	NA	<p>Base case: 60-69 years, repeat test at 2 and 5 years</p> <ul style="list-style-type: none"> • Risedronate EC 35mg 30-DD = \$146,447 60-DD = \$126,578 • Risedronate 5mg 30-DD = \$158,747 60-DD = \$138,880 • Risedronate 150 mg 30-DD = \$142,701 60-DD = \$124,616 • Alendronate 70mg 30-DD = \$89,878 60-DD = \$70,010 • Zoledronic acid 5 mg annual injection \$91,377
DEXA + ARtx (osteoporosis)	\$4,264											
DEXA + ARtx (osteoporosis + osteopenia)	\$20,507											
DEXA + ARtx (osteoporosis)	\$47,556											
DEXA + ARtx (osteoporosis + osteopenia)	\$253,000											
Financial estimates	Total cost of intervention = \$8.6M over 5 years	Cost to MBS over 5 years = \$13.4M for annual DEXA scans and \$10.2M for two yearly scans.	Net financial impact to MBS over 6 years = \$0. Additional scenario 7.5% growth in REMS Year 1 = \$205,576 Year 6 = \$616, 728	Base case: 60-69 years, repeat test at 2 and 5 years Net financial impact to MBS over 6 years = \$134.5M								

	Application 1162	Application 1313	Application 1665	Application 1758
		Total cost to health system = \$19.1M for annual DEXA scans		Net financial impact to PBS over 6 years: <ul style="list-style-type: none"> • Risedronate EC 35mg 30-DD = \$48.6M 60-DD = \$45.5M • Risedronate 5mg 30-DD = \$56.2M 60-DD = \$53.1M • Risedronate 150 mg 30-DD = \$48.3M 60-DD = \$45.3M • Alendronate 70mg 30-DD = \$24.4M 60-DD = \$16.2M • Zoledronic acid 5 mg annual injection = \$12.0M

Source: compiled by the department from the published PSDs

Abbreviations: ARTx = Anti-resorptive therapy; BMD, bone mineral density; CEA, cost-effectiveness analysis; CUA, cost-utility analysis; DEXA, dual energy Xray; LYs, life years; MBS, Medicare Benefits Schedule; NA= not applicable; PSD = Public Summary Document; QALY, quality-adjusted life year; QCT, quantitative computed tomography; REMS, radiofrequency echographic multispectrometry; 30-DD,30 day dispensing; 60-DD, 60 day dispensing

Addendum updated results for PBS medicines: risedronate EC 35mg weekly (also applied to risedronate 35 mg weekly); risedronate 5 mg daily; risedronate 150 mg monthly; alendronate 70 mg weekly and zoledronic acid 5 mg injection year

5. Prerequisites to implementation of any funding advice

There are multiple dual energy x-ray absorptiometry (DEXA) devices and quantitative computed tomography (QCT) systems listed on the ARTG as of July 2023. There are no prerequisites to any funding advice.

6. Proposal for public funding

Current item descriptors for MBS items 12320 and 12322 and proposed amendments are summarised in Table 2 (changes are in blue text). The proposed fee is the same as for all bone densitometry items on the MBS based on the July 2023 schedule. A summary of all MBS items for bone densitometry and relevant explanatory notes are presented in Appendix A of the assessment report.

Table 2 MBS items 12320 and 12322 for bone densitometry with proposed amendments

Category 2 – DIAGNOSTIC PROCEDURES AND INVESTIGATIONS
<p>MBS item 12320</p> <p>Bone densitometry, using dual energy X-ray absorptiometry or quantitative computed tomography, involving the measurement of 2 or more sites (including interpretation and reporting) for measurement of bone mineral density, if:</p> <p>(a) the patient is 60 70 years of age or over, and</p> <p>(b) either:</p> <p>(i) the patient has not previously had bone densitometry; or</p> <p>(ii) the t-score for the patient's bone mineral density is -1.5 or more;</p> <p>other than a service associated with a service to which item 12306, 12312, 12315, 12321 or 12322 applies</p> <p>For any particular patient, once only in a 5 year period</p> <p>Other relevant notes from DN.1.18, Bone Densitometry (Items 12306 to 12322)</p> <p>Fee: \$112.15; Benefit: 75% = \$84.15, 85% = \$95.35</p>
<p>MBS item 12322</p> <p>Bone densitometry, using dual energy X-ray absorptiometry or quantitative computed tomography, involving the measurement of 2 or more sites (including interpretation and reporting) for measurement of bone mineral density, if:</p> <p>(a) the patient is 60 70 years of age or over; and</p> <p>(b) the t-score for the patient's bone mineral density is less than -1.5 but more than -2.5;</p> <p>other than a service associated with a service to which item 12306, 12312, 12315, 12320 or 12321 applies</p> <p>For any particular patient, once only in a 2 year period</p> <p>Other relevant notes from DN.1.18, Bone Densitometry (Items 12306 to 12322)</p> <p>Fee: \$112.15; Benefit: 75% = \$84.15, 85% = \$95.35</p>

7. Population

The proposed population is individuals aged 60 to 69 years with no prior minimal trauma fracture or conditions associated with rapid bone loss. Eligibility criteria are based on current MBS bone densitometry items for individuals aged 70 years and above (item 12320 for individuals with no prior test or BMD T-score is -1.5 or more, and item 12322 for individuals with BMD T-score less than -1.5 but more than -2.5).

8. Comparator

The comparator is standard care (i.e., no testing and standard medical management), including age-appropriate general lifestyle and bone health advice (e.g., exercise, sunshine, diet, calcium and vitamin D supplements when required).

9. Summary of public consultation input

Consultation input was received from five (5) professional organisations and one (1) consumer organisation:

- Australasian Association of Nuclear Medicine Specialists (AANMS)
- Australian Rheumatology Association (ARA)
- Australian Society of Medical Imaging and Radiation Therapy (ASMIRT)
- Healthy Bones Australia
- Queensland Aboriginal and Islander Health Council (QAIHC)
- The Royal Australian College of General Practitioners (RACGP).

The RACGP was not supportive of the proposed amendments to MBS items 12320 and 12322, and recommended the BMD MBS items should continue to align with the evidence-based recommendations outlined in the RACGP's *Osteoporosis prevention, diagnosis and management in postmenopausal women and men over 50* guidance and the *RACGP Guidelines for preventive activities in general practice 9th edition (Red Book)*.

The other five organisations indicated support for the application and feedback noted that:

- The prevalence of poor bone health in the 60-69 age cohort is high.
- Osteoporosis is under-diagnosed as it has no overt symptoms, and it is often not diagnosed until a fracture occurs.

Benefits

- Reducing the age for reimbursed BMD testing will support improved diagnosis and treatment of osteoporosis in this age group, which will help prevent fractures.
- Improving diagnosis and treatment of osteoporosis will assist in reducing the instances of bone fractures and its associated impact on quality of life, in addition to savings for the health system.

Disadvantages /Implementation Issues

- A greater demand on dual energy X-ray absorptiometry (DEXA) services.
- Additional cost.
- Risk of harms from over-screening (Radiation safety aspects).
- Accessibility to the test may be impacted for people who most need and will benefit from receiving the test.

Other Feedback

The Queensland Aboriginal and Islander Health Council (QAIHC) noted that Aboriginal Community Controlled Health Organisations have provided feedback regarding the increase in requests for bone mineral density (BMD) assessments for Aboriginal and Torres Strait Islander peoples aged less than 70 years, with Aboriginal and Torres Strait Islander peoples having a substantially greater fracture risk than non-Indigenous Australians.

DEXA is the preferred tool for assessment of bone density due to lower radiation exposure than quantitative computed tomography and current Medicare item numbers restrict reimbursement for QCT to older individuals over 70 (item numbers 12320 and 12322). Thus, extending the age of the existing item numbers to include 60 to 69 years will require evaluation of the additional radiation exposure to a younger population, compared to the radiation dose of the alternative modality (DEXA).

A comprehensive health assessment (e.g. MBS item 715) would need to be performed for each patient to address other risk factors for osteoporosis.

The RACGP recommended the use of the Fracture Risk Assessment tool (FRAX) to calculate the absolute fracture risk in people aged ≥ 50 years. If bone mineral density (BMD) is indicated, then it should be measured by bone density (DEXA) scanning.

10. Economic evaluation

The economic evaluation is a two-part analysis based on a cost-effectiveness model of universal BMD testing versus no BMD testing in individuals aged 60-69 years, linked to a separate cost-effectiveness model of early versus delayed osteoporosis treatment. The main part of the analysis provides an estimated upfront testing cost (including repeat testing) per additional patient diagnosed with osteoporosis, defined either by BMD criteria or fracture. A supplementary analysis was conducted to assess the cost-effectiveness of early initiation of osteoporosis treatment (detected via BMD testing) in patients aged 60-69 years without fracture versus delayed treatment of patients who have a fracture or reach age 70 years.

The supplementary analysis was based on a cost-effectiveness/cost-utility model previously considered by the PBAC (risedronic acid PSD, November 2022 PBAC meeting with March 2023 Addendum) with the addition of the upfront cost of testing estimated from the first part of the analysis. The PBAC previously considered the risedronic acid economic model to be problematic and may not be reliable for decision making due to multiple concerns with assumptions and inputs, as well as the lack of BMD testing costs (para 7.7, risedronic acid PSD, November 2022 PBAC meeting with March 2023 Addendum). Therefore, the aim of the second part of the economic evaluation is to provide context for the integration of costs associated with BMD testing rather than an endorsement of the approach used in the risedronic acid November 2022 submission.

Cost-effectiveness of BMD testing versus no BMD testing

Table 3 presents a summary of the key components of the economic evaluation.

Table 3 Summary of the economic evaluation

Component	Description
Perspective	Australian healthcare system perspective
Population	Individuals aged 60-69 years who are without fracture or other bone loss related conditions
Intervention	BMD testing versus no BMD testing
Type of analysis	Cost-effectiveness analysis
Outcomes	Additional patients diagnosed with osteoporosis
Time horizon	10 years
Computational method	Markov microsimulation (10,000 trials with specified integer seed value of 1)
Health states	Normal BMD/mild osteopenia, moderate/marked osteopenia, undetected osteoporosis, detected osteoporosis (via BMD), fracture and dead
Cycle length	1 year
Transition probabilities	<p>The baseline distribution of individuals with normal BMD/mild osteopenia, moderate/marked osteopenia and osteoporosis was based on a bespoke analysis of epidemiological data from the Dubbo Osteoporosis Epidemiology Study (DOES). In the BMD testing arm, it was assumed that all individuals are tested in the first cycle, with 100% test accuracy. Therefore, all individuals are assumed to have either detected normal BMD/mild osteopenia, moderate/marked osteopenia or osteoporosis after the initial test.</p> <p>BMD progression transition probabilities were derived from a bespoke analysis of DOES data, assuming a trajectory of normal BMD/mild osteopenia to moderate/marked osteopenia to osteoporosis.</p> <p>Age- and gender-specific fracture risks were derived using mean BMD T-scores for each BMD T-score category, calculated using the Garvan fracture risk calculator assuming all individuals had no prior fracture/falls history.</p> <p>Mortality was based on Australian life tables for the general Australian population aged 60-69 years.</p>
Costs	BMD scan costs were based on September 2023 MBS fees for items 12320 and 12322. The cost of a BMD scan was applied at baseline and at 2- or 5-year intervals depending on eligibility based on the individual's BMD T-score category from the prior test.
Discount rate	5% for both costs and outcomes
Software	TreeAge Pro 2023

Abbreviation: BMD, bone mineral density

The structure of the economic evaluation is based on a Markov microsimulation, consistent with published economic evaluations identified in the literature review. However, a bespoke structure was required in order to model patient trajectories according to BMD T-score categories that determined eligibility for repeat testing as per the proposed MBS items.

In the no BMD testing arm, individuals can either have normal BMD/mild osteopenia, moderate/marked osteopenia or osteoporosis at baseline. In each year, individuals can be without fracture, have a fracture or die. Individuals without fracture can either remain in the same BMD T-score category or progress to the next BMD T-score category based on an assumed trajectory of normal BMD/mild osteopenia (BMD T-score ≥ -1.5) to moderate/marked osteopenia (BMD T-score < -1.5 and > -2.5) to osteoporosis (BMD T-score ≤ -2.5). The BMD T-score thresholds for normal BMD/mild osteopenia and moderate/marked osteopenia were as defined in eligibility criteria for MBS items 12320 and 12322 while the BMD T-score for osteoporosis was based on the WHO definition. The fracture health state was an absorbing health state that captured the modelled outcome of diagnosed osteoporosis via fracture.

In the BMD testing arm, it was assumed that all individuals are tested in the first cycle, with 100% test accuracy (consistent with identified studies in literature review). Therefore, all individuals are assumed to have either detected normal BMD/mild osteopenia, moderate/marked osteopenia or osteoporosis after the initial test. Individuals in the BMD testing arm are at the same risks of BMD progression and fracture as those in the no BMD testing arm. However, individuals without fracture can receive a repeat BMD test at specified intervals (2- or 5-yearly depending on eligibility). The

model structure includes separate osteoporosis health states (based on BMD without fracture) to capture patients with undetected and detected osteoporosis depending on whether they received a BMD test. The model includes trackers that capture each individual's testing history and BMD T-score category, used to determine testing eligibility in each cycle.

The assumptions of 100% test uptake and 100% test accuracy are unlikely to be applicable to clinical practice. However, there were no available data to reliably estimate initial and repeat testing rates or test accuracy in the eligible population without fracture or rapid bone loss conditions. Consequently, the results should be considered the most optimistic estimate of upfront costs based on the incremental cost per additional patient diagnosed with osteoporosis.

A limitation of the model is that it assumed that BMD testing does not have any impact on standard care. For example, having detected osteopenia was assumed to have no change on use of calcium and vitamin D supplements or non-pharmacological interventions such as exercise or smoking cessation. There are known benefits associated with these interventions in terms of fracture prevention that were not captured in this analysis.

Table 4 summarises the results of the economic evaluation.

Table 4 Results of the economic evaluation

Component	BMD test	No BMD test	Increment
Costs	\$255	\$0	\$255
Patients diagnosed with osteoporosis	0.1244	0.0697	0.0547
Incremental cost per additional patient diagnosed with osteoporosis			\$4,673

The results indicate that BMD testing versus no BMD testing, in patients aged 60-69 years without fracture and conditions associated with rapid bone loss, is associated with an incremental cost of \$4,673 per additional patient diagnosed with osteoporosis.

The number needed to test to identify an additional patient with osteoporosis was 47 (calculated as the undiscounted incremental cost per additional patient diagnosed with osteoporosis, \$5,278, divided by the MBS cost per BMD test of \$112.15). This estimate is considerably higher than previously noted by the MSAC Executive based on prevalence data presented in the November 2022 risedronic acid submission (approximate number needed to test of 7 using a rough osteoporosis prevalence of 14.3% weighted by gender in 60-69-year-olds assuming 1 test per person). The number needed to test in the economic evaluation is based on lower prevalence estimates from the DOES analysis in individuals without fracture (between **Redacted%** and **Redacted%**, weighted by gender in 60-69-year-olds) but also included the impact of repeat testing.

Table 5 summarises the incremental costs for health care resources used in the model.

Table 5 Disaggregated costs (discounted) included in the economic evaluation

Item	BMD test	No BMD test	Incremental cost
Initial test	\$112.15	-	\$112.15
Repeat test	\$143.63	-	\$143.63
- 2 yearly	\$90.41	-	\$90.41
- 5 yearly	\$53.22	-	\$53.22
Total	\$255.79	-	\$255.79

The incremental cost was driven by costs associated with BMD testing, with no other costs included in the base case. A greater proportion of the incremental cost was associated with repeat testing, particularly 2-yearly repeat testing.

Table 6 summarises the health outcomes included in the model.

Table 6 Disaggregated health outcomes included in the economic evaluation

Item	BMD test	No BMD test	Increment
Patients with diagnosed osteoporosis (undiscounted)	0.1465	0.0907	0.0558
- Detected via BMD (undiscounted)	0.0693	0	0.0693
- Detected via fracture (undiscounted)	0.0772	0.0907	-0.0135
Patients with undiagnosed osteoporosis (undiscounted)	0.0005	0.0680	-0.0675
Dead (undiscounted)	0.0656	0.0676	-0.0020
Patients with diagnosed osteoporosis (discounted)	0.1244	0.0697	0.0547

Note: The total time spent with normal BMD/mild osteopenia, moderate/marked osteopenia or undetected osteoporosis (undiscounted) was 8.3350 years for individuals in the BMD test arm and 7.8005 years in the no BMD test arm (difference of -0.5345 years)

The difference in health outcomes was driven by the increased proportion of patients diagnosed with osteoporosis through BMD testing. The proportion of patients with undiagnosed osteoporosis in the BMD test arm was relatively small given the assumption of 100% test uptake and 100% test accuracy.

There were fewer patients diagnosed with osteoporosis due to fracture in the BMD test arm as well as a relatively small difference in mortality compared to the no BMD test arm. This was due to modelled outcomes based on patients diagnosed with osteoporosis, detected via BMD or fracture in the BMD test arm and only via fracture in the no BMD test arm. Patients diagnosed with osteoporosis were no longer at risk of fracture or mortality in the model (i.e. detected osteoporosis and fracture are absorbing health states). This was a simplifying approach that had minimal impact on modelled outcomes given the relatively low risks of fracture and mortality in the modelled population.

Table 7 summarises the key drivers of the economic model.

Table 7 Key drivers of the model

Description	Method/Value	Impact
Frequency of repeat testing	Testing frequencies were either 2-yearly or 5-yearly depending on eligibility based on the individual's BMD T-score from the prior test. Disaggregated costs and health outcomes indicated that the incremental cost was driven by costs associated with repeat testing, particularly 2-yearly repeat testing. There were also relatively few additional patients with osteoporosis detected via BMD testing after the initial test at baseline.	High, lower testing frequency favours BMD testing
Age threshold	The proposed age threshold was 60 years. Scenario analyses indicated that a higher age threshold of 65 years is associated with substantially reduced upfront costs per additional patient identified with osteoporosis.	High, higher age threshold favours BMD testing

The results of key sensitivity analyses are summarised in Table 8 below.

Table 8 Sensitivity analyses

Analyses	Incremental cost	Incremental outcome	ICER	% change in ICER
Base case	\$255	0.0547	\$4,673	-
Discounting (base case 5%)				
0%	\$294	0.0558	\$5,278	+13%
3.5%	\$266	0.0551	\$4,829	+3%
Time horizon (base case 10 years)				
5 years	\$162	0.0587	\$2,770	-41%
Baseline BMD T-score distribution (base case derived from y analysis, all patients at study entry)				
DOES analysis, subgroup with baseline and repeat test	\$255	0.0473	\$5,404	+16%
Testing interval (base case initial test at age 60 years and repeat testing at 2- or 5-yearly intervals)				
Initial test and 5-yearly repeat tests	\$187	0.0538	\$3,483	-25%
Initial test and no repeat tests	\$112	0.0523	\$2,144	-54%

Abbreviations: ICER, incremental cost-effectiveness ratio

The economic evaluation was most sensitive to alternative testing intervals and time horizon.

Table 9 summarises results of scenario analyses using an older age band (65-69 years) and alternative testing intervals.

Table 9 Results of the scenario analyses

Analyses	Incremental cost	Incremental outcome	ICER
Base case	\$255	0.0547	\$4,673
Age 65-69 years, initial test followed by repeat testing at 2-yearly intervals for those with moderate/marked osteopenia, 5 year time horizon	\$163	0.1039	\$1,576
Age 65-69 years, initial test at baseline only, 5 year time horizon	\$112	0.0972	\$1,154

Note: The baseline BMD T-score distribution for the scenario analyses was based on patients aged 65-69 years in the Dubbo Osteoporosis Epidemiology Study (DOES) analysis

The results indicate improved cost-effectiveness when the age threshold is increased to 65 years, particularly when testing is based on a single test at the qualifying age only.

Cost-effectiveness of early versus delayed treatment of osteoporosis (supplementary analysis)

The economic model is based on the model presented in the November 2022 risedronic acid submission to the PBAC.

For simplicity, the risedronate sodium 35 mg once weekly enteric coated (EC) formulation is referred to as risedronate EC in this section.

The risedronic acid submission's economic evaluation was based on early initiation of treatment with risedronate EC in patients aged less than 70 years with a BMD T-score of -2.5 or less, who are without fracture, versus delayed treatment with standard care therapies (predominantly denosumab) in patients who fracture or reach the age of 70 years. The modelled population was synthesised using epidemiological data, with fracture risks estimated using the Garvan risk calculator, treatment effects derived from subgroups of the alendronate (FIT-CFA) and denosumab (FREEDOM) placebo-controlled trials as well as other modelled variables. The economic evaluation was presented as a cost-effectiveness/cost-utility analysis.

Key differences with the November 2022 risedronic acid submission are the inclusion of the costs associated with BMD testing to identify patients with osteoporosis eligible for treatment and amendment to population characteristics consistent with the proposed population.

Table 10 summarises the results of the modelled economic evaluation.

Table 10 Results of the economic evaluation

Component	Risedronate EC	Delayed initiation of standard care	Increment
Outcome: fractures			
Costs	\$12,490	\$8,037	\$4,453
Fractures	0.2576	0.2835	-0.0259
Incremental cost/fracture avoided			\$171,951
Outcome: QALYs			
Costs	\$12,490	\$8,037	\$4,453
QALYs	9.2425	9.2121	0.0304
Incremental cost/QALY gained			\$146,385

Abbreviations: EC, enteric coated; QALY, quality adjusted life year

Based on the economic model, early risedronate EC was associated with an incremental cost per QALY gained of \$146,387 compared to delayed initiation of standard care treatment for osteoporosis in patients aged 60 to 69 years. This estimate should be considered optimistic, given the model base case assumes perfect treatment persistence over the 20-year time horizon, includes upfront BMD testing costs assuming 100% uptake and 100% accuracy, and assumes 100% treatment uptake in patients diagnosed with osteoporosis.

This compares to an incremental cost per QALY gained of **\$redacted** in the November 2022 risedronic acid submission (which did not include the costs of BMD testing to identify patients with osteoporosis; included a younger population (62 versus 65 years), with a smaller proportion of males (15% versus 29%); and was based on a higher price of risedronate EC (DPMQ of \$36.09 in April 2022 compared with \$33.41 in October 2023).

The incremental cost was driven by the costs associated with BMD testing to identify patients with osteoporosis. Scenario analyses using alternative BMD testing scenarios and/or limiting the population to patients aged 65 to 69 years, resulted in more favourable incremental cost-effectiveness ratios (ICERs).

Based on the model output, the number needed to treat (NNT) to prevent any fracture is 39, the NNT to prevent a hip fracture is 97 and to prevent a non-hip fracture 65. These estimates are considerably higher than the NNTs reported in the November 2022 risedronic acid submission (NNT to prevent any fracture 20; hip fracture 57; non-hip fracture 31) due to differences in patient characteristics (mean age 65 years and 29% male in the current model, compared with a mean age of 62 years and **Redacted**% male in the November 2022 risedronic acid submission).

Table 11 presents the results of sensitivity analyses. The analyses were focussed on issues raised by the ESC of PBAC previously, as well as key drivers of the current model, that included modifications to the patient population and incorporation of imperfect treatment persistence.

Table 11 Results of sensitivity analyses

	Incremental cost	Incremental QALYs	ICER	% change in ICER
Base case	\$4,453	0.0304	\$146,385	-
Discount rate (base case 5%)				
0%	\$3,756	0.0521	\$72,150	-50.7%
3.5%	\$4,293	0.0354	\$121,365	-17.1%
Time horizon (base case 20 years)				
5 years	\$5,502	0.0069	\$799,020	+445.8%
10 years	\$4,992	0.0149	\$334,878	+128.8%
15 years	\$4,654	0.0228	\$203,998	+39.4%
Baseline age and BMD T-score (base case mean age 65 years, BMD T-score -2.5)				
60 years; BMD T-score -2.5	\$5,353	0.0457	\$117,083	-20.0%
60 years; BMD T-score -3.0	\$4,766	0.0619	\$77,035	-47.4%
62 years; BMD T-score -2.5	\$5,006	0.0417	\$120,134	-17.9%
62 years; BMD T-score -3.0	\$4,504	0.0565	\$79,693	-45.6%
65 years; BMD T-score -3.0	\$4,125	0.0414	\$99,693	-31.9%
67 years; BMD T-score -2.5	\$4,079	0.0173	\$235,280	+60.7%
67 years; BMD T-score -3.0	\$3,916	0.0235	\$166,311	+13.6%
Fracture treatment effects (base case RRR for risedronate: 56% for hip fracture and 35% for non-hip fracture; SC: 55% for hip fracture and 34% for non-hip fracture)				
RRR for risedronate EC 41% for hip fracture and 46% for non-hip fracture (Boonen et al., 2010)	\$4,541	0.0287	\$158,221	+8.1%
RRR equivalent for risedronate EC and SC: 41% for hip fracture and 46% for non-hip fracture (Boonen et al., 2010)	\$4,518	0.0292	\$154,808	+5.8%
Fracture-related mortality multiplier (base case hip: 2.43, non-hip: 1.65; applied to all fracture states)				
Applied for 1 year, new fracture states only	\$4,404	0.0201	\$219,389	+49.9%
Drug costs (base case early initiation of risedronate EC versus delayed initiation of standard care, based on 30 day dispensing)				
Assume 60 day dispensing of risedronate and alendronate	\$3,820	0.0304	\$125,598	-14.2%
Assume alendronate cost for cost of risedronate EC (30 day dispensing)	\$2,786	0.0304	\$91,596	-37.4%
Assume alendronate cost for cost of risedronate EC (60 day dispensing)	\$2,155	0.0304	\$70,842	-51.6%
Persistence (base case: perfect persistence to risedronate EC and delayed SC over the 20 year time horizon)				
Persistence assuming patients initiate osteoporosis treatment once in a lifetime	\$4,609	-0.0139	Risedronate EC dominated	-
Persistence assuming patients may initiate osteoporosis treatment more than once in a lifetime	\$3,964	0.0082	\$483,223	+230.1%
Treatment switch to SC (base case risedronate arm: patients with fracture switch to SC, delayed SC arm: patients who reach age 70 years or fracture switch to SC)				
Patients without fracture in both arms switch to SC at age 70 years ^a	\$5,313	0.0304	\$174,677	+19.3%
First year fracture costs (base case hip fracture: \$41,626, non-hip fracture: \$11,170)				
Proposed by the ESC of PBAC (40% reduction in new hip and non-hip fracture costs)	\$4,657	0.0304	\$153,099	+4.6%
Proposed by sponsor in Pre-PBAC Response (6% reduction in new hip and non-hip fracture costs)	\$4,483	0.0304	\$147,392	+0.7%

Abbreviations: EC, enteric coated; ICER, incremental cost effectiveness ratio; QALY, quality adjusted life year; RRR, relative risk reduction; SC, standard care

^a This sensitivity analysis only affects costs, as treatment effects for the risedronate EC arm are based on SC treatment effects from age 70 years in the model base case.

Addendum

The MSAC ESC also requested additional analyses presenting results for cost-effectiveness and financial impact, based on 5 different age range/repeat testing scenarios for the base case as well as sensitivity analyses for the economic evaluation using a 10 year time horizon and/or imperfect persistence. Imperfect persistence scenarios were conducted assuming patients who discontinue treatment would reinitiate treatment (using standard care) if they experienced a fracture or in the absence of fracture, once they reached age 70 years.

Treatment persistence estimates were derived from median durations of therapy from the DUSC review of denosumab, October 2020 report. Due to the existing model structure, persistence estimates were applied to transitions from the no fracture state only, with perfect persistence assumed for transitions from the new/prior fracture health states due to the inability to track when the fracture occurred to apply varying persistence estimates. It was assumed that there were no residual treatment effects following treatment discontinuation.

The economic evaluation was updated using current PBS prices (April 2024 PBS Schedule). The financial estimates were updated using current PBS prices (April 2024 PBS Schedule), updated PBS copayments (January 2024) and copayment distribution data from January 2023 to December 2023 allowing for a full year of data based on the introduction of the lower \$30 general copayment in January 2023.

Separate analyses were conducted based on 30- and 60-day dispensing items. Average patient copayments for 60-day dispensing items were based on 30-day dispensing data given limited PBS utilisation data for 60-day dispensing items (introduced from September 2023).

The above analyses were conducted for the main analyses based on risedronate EC and then repeated, based on risedronate EC circumstances of use, for:

- risedronate 5 mg daily
- risedronate 150 mg monthly
- alendronate 70 mg weekly
- zoledronic acid 5 mg injection yearly

The cost-effectiveness and financial impact of risedronate 35 mg weekly (non-enteric coated formulation) were assumed to be the same as estimated for the main analyses based on risedronate EC weekly as both listings had the same price as of April 2024.

Results for the various analyses are presented in the tables below.

Table 12 Risedronate EC 35 mg weekly (also applies to risedronate 35 mg weekly); Shaded represents ESCs respecified base case

Possible testing scenario			Economic evaluation					Budget impact over 6 years	
Age range	Repeat test at 2 years?	Repeat test at 5 years?	Cost per additional osteoporosis diagnosis	Cost per QALY gained				MBS	PBS
				Base case	10 year time horizon	Imperfect persistence ^a	10 year time horizon and imperfect persistence		
30-day dispensing (DPMQ \$33.41)									
60-69 years	Yes	Yes	\$4,673	\$146,447	\$334,940	\$616,741	\$1,180,269	\$134,505,759	\$48,607,326
60-69 years	No	Yes	\$3,483	\$107,324	\$255,109	\$471,689	\$904,309	\$104,985,636	\$37,112,730
60-69 years	No	No	\$2,144	\$63,303	\$165,283	\$308,474	\$593,796	NE ^b	NE ^b
65-69 years	Yes	N/A	\$1,576	\$54,680	\$156,692	\$259,089	\$497,964	\$65,383,476	\$29,733,580
65-69 years	No	N/A	\$1,154	\$30,993	\$110,182	\$201,101	\$387,733	\$51,022,041	\$22,701,137
60-day dispensing (DPMQ \$53.83)									
60-69 years	Yes	Yes	\$4,673	\$126,578	\$306,236	\$605,702	\$1,159,233	\$134,505,759	\$45,530,387
60-69 years	No	Yes	\$3,483	\$87,455	\$226,405	\$460,650	\$883,273	\$104,985,636	\$34,763,421
60-69 years	No	No	\$2,144	\$43,434	\$136,578	\$297,435	\$572,760	NE ^b	NE ^b
65-69 years	Yes	N/A	\$1,576	\$22,647	\$111,949	\$248,255	\$477,340	\$65,383,476	\$27,851,385
65-69 years	No	N/A	\$1,154	Dominant	\$65,438	\$190,268	\$367,109	\$51,022,041	\$21,264,111

Abbreviations: DPMQ, dispensed price maximum quantity; MBS, Medicare Benefits Schedule; N/A, not applicable; NE, not estimable; PBS, Pharmaceutical Benefits Scheme; QALY, quality adjusted life year

^a Assumes that patients who discontinue treatment reinitiate treatment using standard care if they experienced a fracture or in the absence of fracture, once they reached age 70 years.

^b Not estimable as testing rates based on MBS item numbers do not differentiate between initial and repeat testing.

Table 13 Risedronate 5 mg daily; Shaded represents ESCs respecified base case; Shaded represents ESCs respecified base case

Possible testing scenario			Economic evaluation					Budget impact over 6 years	
Age range	Repeat test at 2 years?	Repeat test at 5 years?	Cost per additional osteoporosis diagnosis	Cost per QALY gained				MBS	PBS
				Base case	10 year time horizon	Imperfect persistence ^a	10 year time horizon and imperfect persistence		
30-day dispensing (DPMQ \$37.00)									
60-69 years	Yes	Yes	\$4,673	\$158,747	\$352,173	\$622,870	\$1,191,929	\$134,505,759	\$56,242,980
60-69 years	No	Yes	\$3,483	\$119,624	\$272,342	\$477,818	\$915,969	\$104,985,636	\$42,942,715
60-69 years	No	No	\$2,144	\$75,603	\$182,516	\$314,603	\$605,456	NE ^b	NE ^b
65-69 years	Yes	N/A	\$1,576	\$75,056	\$184,635	\$265,101	\$509,393	\$65,383,476	\$34,404,384
65-69 years	No	N/A	\$1,154	\$51,370	\$138,125	\$207,113	\$399,162	\$51,022,041	\$26,267,226
60-day dispensing (DPMQ \$61.01)									
60-69 years	Yes	Yes	\$4,673	\$138,880	\$323,471	\$611,832	\$1,170,894	\$134,505,759	\$53,102,416
60-69 years	No	Yes	\$3,483	\$99,757	\$243,640	\$466,779	\$894,934	\$104,985,636	\$40,544,827
60-69 years	No	No	\$2,144	\$55,736	\$153,813	\$303,565	\$584,421	NE ^b	NE ^b
65-69 years	Yes	N/A	\$1,576	\$43,026	\$139,896	\$254,268	\$488,770	\$65,383,476	\$32,483,270
65-69 years	No	N/A	\$1,154	\$19,339	\$93,385	\$196,281	\$378,539	\$51,022,041	\$24,800,485

Abbreviations: DPMQ, dispensed price maximum quantity; MBS, Medicare Benefits Schedule; N/A, not applicable; NE, not estimable; PBS, Pharmaceutical Benefits Scheme; QALY, quality adjusted life year

^a Assumes that patients who discontinue treatment reinitiate treatment using standard care if they experienced a fracture or in the absence of fracture, once they reached age 70 years.

^b Not estimable as testing rates based on MBS item numbers do not differentiate between initial and repeat testing.

Table 14 Risedronate 150 mg monthly; Shaded represents ESCs respecified base case

Possible testing scenario			Economic evaluation					Budget impact over 6 years	
Age range	Repeat test at 2 years?	Repeat test at 5 years?	Cost per additional osteoporosis diagnosis	Cost per QALY gained				MBS	PBS
				Base case	10 year time horizon	Imperfect persistence ^a	10 year time horizon and imperfect persistence		
30-day dispensing (DPMQ \$35.13)									
60-69 years	Yes	Yes	\$4,673	\$142,701	\$329,692	\$614,875	\$1,176,718	\$134,505,759	\$48,128,090
60-69 years	No	Yes	\$3,483	\$103,578	\$249,861	\$469,822	\$900,758	\$104,985,636	\$36,746,823
60-69 years	No	No	\$2,144	\$59,557	\$160,035	\$306,608	\$590,245	NE ^b	NE ^b
65-69 years	Yes	N/A	\$1,576	\$48,475	\$148,183	\$257,258	\$494,484	\$65,383,476	\$29,440,426
65-69 years	No	N/A	\$1,154	\$24,788	\$101,672	\$199,270	\$384,253	\$51,022,041	\$22,477,319
60-day dispensing (DPMQ \$57.27)									
60-69 years	Yes	Yes	\$4,673	\$124,616	\$303,487	\$604,724	\$1,157,373	\$134,505,759	\$45,290,258
60-69 years	No	Yes	\$3,483	\$85,493	\$223,656	\$459,672	\$881,413	\$104,985,636	\$34,580,078
60-69 years	No	No	\$2,144	\$41,472	\$133,829	\$296,457	\$570,900	NE ^b	NE ^b
65-69 years	Yes	N/A	\$1,576	\$19,396	\$107,491	\$247,296	\$475,517	\$65,383,476	\$27,704,497
65-69 years	No	N/A	\$1,154	Dominant	\$60,981	\$189,309	\$365,286	\$51,022,041	\$21,151,963

Abbreviations: DPMQ, dispensed price maximum quantity; MBS, Medicare Benefits Schedule; N/A, not applicable; NE, not estimable; PBS, Pharmaceutical Benefits Scheme; QALY, quality adjusted life year

^a Assumes that patients who discontinue treatment reinitiate treatment using standard care if they experienced a fracture or in the absence of fracture, once they reached age 70 years.

^b Not estimable as testing rates based on MBS item numbers do not differentiate between initial and repeat testing.

Table 15 Alendronate 70 mg weekly; Shaded represents ESCs respecified base case

Possible testing scenario			Economic evaluation					Budget impact over 6 years	
Age range	Repeat test at 2 years?	Repeat test at 5 years?	Cost per additional osteoporosis diagnosis	Cost per QALY gained				MBS	PBS
				Base case	10 year time horizon	Imperfect persistence ^a	10 year time horizon and imperfect persistence		
30-day dispensing (DPMQ \$16.90)									
60-69 years	Yes	Yes	\$4,673	\$89,878	\$255,688	\$588,555	\$1,126,645	\$134,505,759	\$24,366,033
60-69 years	No	Yes	\$3,483	\$50,756	\$175,857	\$443,503	\$850,685	\$104,985,636	\$18,603,986
60-69 years	No	No	\$2,144	\$6,734	\$86,031	\$280,288	\$540,173	NE ^b	NE ^b
65-69 years	Yes	N/A	\$1,576	Dominant	Dominant	\$215,894	\$415,854	\$65,383,476	\$14,904,942
65-69 years	No	N/A	\$1,154	Dominant	Dominant	\$157,906	\$305,622	\$51,022,041	\$11,379,698
60-day dispensing (DPMQ \$20.81)									
60-69 years	Yes	Yes	\$4,673	\$70,010	\$226,985	\$577,516	\$1,105,610	\$134,505,759	\$16,247,487
60-69 years	No	Yes	\$3,483	\$30,888	\$147,154	\$432,464	\$829,650	\$104,985,636	\$12,405,303
60-69 years	No	No	\$2,144	Dominant	\$57,328	\$269,249	\$519,137	NE ^b	NE ^b
65-69 years	Yes	N/A	\$1,576	Dominant	Dominant	\$220,607	\$424,782	\$65,383,476	\$9,938,748
65-69 years	No	N/A	\$1,154	Dominant	Dominant	\$162,619	\$314,551	\$51,022,041	\$7,588,083

Abbreviations: DPMQ, dispensed price maximum quantity; MBS, Medicare Benefits Schedule; N/A, not applicable; NE, not estimable; PBS, Pharmaceutical Benefits Scheme; QALY, quality adjusted life year

^a Assumes that patients who discontinue treatment reinitiate treatment using standard care if they experienced a fracture or in the absence of fracture, once they reached age 70 years.

^b Not estimable as testing rates based on MBS item numbers do not differentiate between initial and repeat testing.

Table 16 Zoledronic acid 5 mg annual injection (DPMQ \$74.52); Shaded represents ESCs respecified base case

Possible testing scenario			Economic evaluation					Budget impact over 6 years	
Age range	Repeat test at 2 years?	Repeat test at 5 years?	Cost per additional osteoporosis diagnosis	Cost per QALY gained				MBS	PBS
				Base case	10 year time horizon	Imperfect persistence ^a	10 year time horizon and imperfect persistence		
60-69 years	Yes	Yes	\$4,673	\$91,377	\$257,788	\$576,727	\$1,055,798	\$150,678,695	\$12,010,658
60-69 years	No	Yes	\$3,483	\$52,254	\$177,957	\$434,694	\$797,289	\$117,334,018	\$9,170,394
60-69 years	No	No	\$2,144	\$8,233	\$88,130	\$274,877	\$506,411	NE ^b	NE ^b
65-69 years	Yes	N/A	\$1,576	Dominant	\$31,590	\$184,609	\$348,686	\$75,276,620	\$7,347,038
65-69 years	No	N/A	\$1,154	Dominant	Dominant	\$138,165	\$262,259	\$58,575,307	\$5,609,352

Abbreviations: DPMQ, dispensed price maximum quantity; MBS, Medicare Benefits Schedule; N/A, not applicable; NE, not estimable; PBS, Pharmaceutical Benefits Scheme; QALY, quality adjusted life year

^a Assumes that patients who discontinue treatment reinitiate treatment using standard care if they experienced a fracture or in the absence of fracture, once they reached age 70 years.

^b Not estimable as testing rates based on MBS item numbers do not differentiate between initial and repeat testing.

Note 1: Cost-effectiveness and financial estimates were based on alternative persistence/duration of treatment estimates

Note 2: MBS costs include zoledronic acid administration costs assuming one specialist visit per year (\$76.08 based on item 104 at 80% benefit, September 2023 MBS Schedule)

Overall, scenarios based on a higher age threshold and reduced frequency or removal of repeat testing, produced more favourable results in terms of the economic evaluation and budget impact.

The base case economic evaluation was based on a 20-year time horizon and assumed 100% treatment persistence. Alternative time horizons (5, 10 and 15 years) and imperfect persistence scenarios had large impacts on the economic analysis, primarily due to reductions in incremental QALY gains that were associated with fractures avoided and time spent in the fracture health states. Similar patterns were observed based on scenario analyses using various age ranges and alternative frequencies or removal of repeat testing.

The reliability of results based on imperfect persistence scenarios is uncertain given the implementation of treatment persistence was limited by the model structure. The validity of treatment duration estimates was also uncertain given limited reporting (e.g. no measures of variance) in the publicly available DUSC report and no other published estimates for time to treatment discontinuation based on contemporary data in the Australian setting could be identified during the preparation of the DCAR.

11. Financial/budgetary impacts

An epidemiological approach was used to estimate the extent of use and financial implications of extending BMD testing to individuals aged 60-69 years under the MBS.

During the preparation of the assessment report, it was noted that there were insufficient contemporary Australian data to inform a detailed epidemiology-based model on expected utilisation. Therefore, a simplified approach was taken by extrapolating testing rates in the existing population (individuals aged 70 years or older) and applying these estimates to the target population (individuals aged 60-69 years).

Testing rates in the existing population were estimated based on ABS data on the size of the Australian population by age and gender in 2018-2022. These estimates were then compared with MBS data on the age and gender of individuals using BMD scanning items (MBS 12320, MBS 12322) over the same time period.

The estimated extent of use and financial implications of expanding the eligibility of BMD testing items to younger individuals aged 60-69 years are summarised in Table 17.

Table 17 Net financial implications of expanding BMD testing items to include younger individuals aged 60-69 years

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Total patients aged 60-69 years undergoing BMD testing	230,771	233,066	234,667	235,901	237,221	239,028
Total MBS cost	\$22,003,978	\$22,222,797	\$22,375,462	\$22,493,180	\$22,619,049	\$22,791,293

Abbreviations: BMD, bone mineral density; MBS, Medicare Benefits Schedule

Expanding the population eligible for BMD testing would increase the annual number of scans conducted from 230,771 in Year 1 to 239,028 in Year 6. For comparison, the total number of BMD scans conducted in 2022 for the existing population aged 70 years or older was 249,996.

The estimated net cost to the MBS for extending BMD testing to a younger population was \$22.0 million in Year 1, increasing to \$22.8 million in Year 6, with a cumulative total of \$134.5 million over 6 years.

The uncertainty associated with the estimated budget impact of expanded BMD testing was explored in sensitivity analyses (shown in Table 18).

Table 18 Key sensitivity analyses of BMD testing

Analyses	Cumulative cost to MBS over 6 years
Base case	\$134,505,759
Delayed uptake of BMD testing which increases over time using a linear trend to achieve rates in 70-74 year olds by Year 6	\$78,898,614
Delayed uptake of BMD testing which increases over time using a linear trend to achieve rates in 70-74 year olds by Year 3	\$112,428,841
No use of 2-year testing for any patient aged 60-69 years	\$104,985,636
BMD testing restricted to 65-69 year olds	\$65,383,476
BMD testing restricted to 65-69 year olds with no 2-year testing	\$51,022,041
Higher testing rates in patients aged 60-69 years based on a linear extrapolation of testing rates across older age groups	\$173,732,482

Abbreviations: BMD, bone mineral density; MBS, Medicare Benefits Schedule

The results of the sensitivity analyses indicated that the budget impact estimate was most sensitive to the uptake rate of BMD testing over time and the age band eligible for testing.

The yearly net financial implications of expanding BMD testing to include younger individuals aged 65-69 years is summarised in Table 19.

Table 19 Net financial implications of expanding BMD testing items to include younger individuals aged 65-69 year

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Total patients aged 65-69 years undergoing BMD testing	108,652	111,124	113,596	115,841	117,622	108,652
Total MBS cost	\$10,359,993	\$10,595,719	\$10,831,410	\$11,045,463	\$11,215,298	\$10,359,993
Total patients aged 65-69 years with no 2-year testing	84,791	86,718	88,640	90,396	91,788	84,791
Total MBS cost	\$8,084,863	\$8,268,567	\$8,451,855	\$8,619,212	\$8,752,020	\$8,845,524

Source: Compiled by department from Sensitivity Analyses tab of financial spreadsheet (BMD financial estimates_updated 2024-05-15)

Addendum

The MSAC ESC requested further clarification regarding the methodology used for the financial analyses, including:

1. Whether it could be separated for repeat testing at 2 and 5 year intervals which would improve transparency of the modelling of initial and repeat testing.

The assessment group advised that the utilisation estimates in the younger population were derived from utilisation data from the 70–74 year old age band, which would only include 1 initial test using the 5-year testing item and a maximum of 2 repeats using the 2-year testing item. There is no further potential to separate the available utilisation data.

2. Whether utilisation of MBS items 12315 and 12321 (by respective age groups) needed to be accounted for (i.e. excluded) in the utilisation estimates as some patients in the proposed expanded population may be able to access BMD testing under these items already.

The assessment group advised that the utilisation of MBS items 12315 and 12321 would already impact the utilisation of the 5-year and 2-year testing items in the 70–74 year old age band, which was used as the basis for modelled projections. The utilisation estimates make an implicit assumption that the utilisation of these MBS items will be broadly similar between the 60–69 year old age band and the 70-74 year old age band.

The cumulative cost for BMD testing to the MBS over 6 years was unchanged in the Addendum results, except for the MBS financial estimates for zoledronic acid, which also included administration costs (\$76.08 at 80% benefit item 104 specialist visit, September 2023 MBS Schedule [\$95.10]) based on yearly intravenous costs that were included in the economic model. See tables 12-16 above in Section 10.

The cumulative cost over 6 years to the PBS for the various osteoporosis medicines (risedronate EC (Table 12,) risedronate 5 mg daily (Table 13), risedronate 150 mg monthly (Table 14), alendronate 70 mg weekly (Table 15), zoledronic acid 5 mg injection yearly (Table 16) are summarised above in Section 10.

12. Other relevant information

Nil.

13. Key issues from ESC to MSAC

Main issues for MSAC consideration

No additional issues, to those previously outlined in the Ratified MSAC ESC report for application 1758 from February 2024, have been identified in the additional analyses performed in the Addendum. Thus, the main issues for the proposed expansion of BMD testing for MSAC consideration relate to those issues already identified by the MSAC ESC, as outlined below:

Economic issues:

- The model structure relied on assumptions of 100% test uptake and 100% test accuracy, which are unlikely to be realised in clinical practice. However, there were no available data to reliably estimate uptake levels or test accuracy in the target population. Consequently, the estimated upfront cost associated with BMD testing should be considered the most optimistic estimate.
- Results from the base case analysis indicated a number needed to test of 47 to identify an additional patient with osteoporosis, based on the proposed eligibility criteria for 2- and 5-yearly BMD tests. Alternative scenarios based on a higher age threshold and reduced frequency or removal of repeat testing produced more favourable ICERs. As above, the expansion of BMD testing to those of 65-69 years of age with no repeat BMD testing was considered the respecified base case and most relevant for decision making.

Financial issues:

- The modelled testing scenario with the most favourable cost-effectiveness and lowest financial impact is expanding MBS items 13230 and 12322 to people aged 65–69 years with no option for repeat testing until the age of 70.
- There are limited data to estimate the utilisation of BMD testing in populations younger than 70 years of age. The analysis depended on the extrapolation of BMD testing rates in older populations to younger populations, which may not reflect likely clinical practice.
- There has been significant increase in utilisation of the BMD items listed on the MBS which may mean that the BMD testing expenditure through the budget impact may be larger than estimated.

ESC discussion

The PBAC ESC and MSAC ESC (hereafter 'ESCs') noted that in February 2024, the MSAC ESC considered Department Contracted Assessment Report (DCAR) for application 1758. The ESCs noted that, to address some outstanding uncertainties, the MSAC ESC had requested additional work for the assessment to subsequently be jointly considered by the ESCs. The ESCs noted that the primary areas of concern were related to the incremental cost-effectiveness ratios (ICERs),

budget impact analyses and methodology used for the financial analyses if MBS items 13230 and 12322 were expanded to include the 60-69 age range for bone mineral densitometry (BMD) testing. The ESCs noted this additional work was completed through the Addendum to the DCAR, included in Section 7 (Economic Evaluation) and Section 8 (Financial impacts) of this report.

The ESCs noted the Addendum provided a summary table of ICERs and budget impact analyses to inform MSAC advice on expanding MBS items 13230 and 12322, and the PBAC's reconsideration of its deferred advice from the Osteoporosis Therapy Restrictions Review in September 2021.

The ESCs noted the ICERs in the summary tables in the Addendum were based on five different age range/repeat testing scenarios for the cost-effectiveness analysis (CEA) [Part A of the economic analysis] which estimated the cost per additional patient diagnosed with osteoporosis with the proposed expansion of BMD testing. In addition, the summary tables provided sensitivity analyses for the cost-utility analysis (CUA) [Part A & B of the economic analysis] of early versus delayed osteoporosis treatment using a 10 year time horizon and/or imperfect persistence. An imperfect persistence scenario was conducted assuming patients who discontinue treatment would reinstate treatment (using standard care) if they experienced a fracture or in the absence of fracture, once they reached age 70 years (i.e. patients may initiate osteoporosis treatment more than once in their lifetime). The ESCs noted that the results of the CEA [Part A of the economic analysis] were unchanged in the Addendum and thus the issues for BMD testing were the same as those identified by the MSAC ESC in February 2024. The ESCs noted the CUA was updated for current PBS price for risedronate EC, and also expanded to model cost-effectiveness of other relevant osteoporosis medicines included in the PBAC Osteoporosis Therapy Restrictions Review (based on the risedronate EC circumstances of use). The ESCs considered that because the CUA analysis linked test to health outcomes that it would be more relevant for decision making than the CEA.

The ESCs noted that the risedronate enteric coated (EC) 35mg – 30-day dispensing model for 60-69 years with repeat testing at 2- and 5-years (base case) results in an incremental cost per additional osteoporosis diagnosis of \$4,673 and an ICER of \$146,447 per QALY gained. The ESCs considered that as per previous discussions, the relevance of a 2-year repeat testing is unclear due to minimal changes in BMD being visible on a dual-energy X-ray absorptiometry (DEXA) scan in the proposed population for expansion. Furthermore, the ESCs considered that BMD loss can be very slow and it may take approximately five years before a change can be detected by DEXA. However, the ESCs noted that if patients underwent an initial test at 65 years, with an absence of other significant symptoms or conditions, they would be eligible for future MBS-funded BMD scans from 70 years of age, so there would unlikely be a service gap if repeat testing was clinically warranted. Thus, the ESCs noted that the removal of repeat testing at 2-years for the 60-69 years age group reduces the incremental cost per additional osteoporosis diagnosis to \$3,483 and an ICER of \$107,324 per QALY gained. The ESCs noted that the scenario for the 65-69 aged group for risedronate EC with no repeat testing at 2-years (or 5-years as patients would default to pre-established aged <70 inclusion on the MBS) resulted in an incremental cost per additional osteoporosis diagnosis of \$1,154 and an ICER of \$30,993. The ESCs noted that under this scenario (65- 69 years with no repeat testing) that the risedronate EC (60 day dispensing), risedronate 150 mg monthly (60-day dispensing), alendronate 70 mg weekly (30 day and 60 day dispensing) and zoledronic acid 5 mg weekly models were dominant (i.e. more effective and less costly).

The ESCs recalled that the economic model used in the DCAR and subsequent scenarios presented in the Addendum is based on the model presented in the November 2022 risedronic acid submission to PBAC. The ESCs noted the PBAC had previously considered the risedronic acid submission economic model to be problematic primarily due to concerns regarding the lack of BMD testing costs, assumptions of perfect treatment persistence over the 20-year time horizon,

use of alendronate as a proxy to determine risedronate treatment effects and overestimating the cost of fractures occurring in the younger population (para 7.7, risedronic acid PSD, November 2022 PBAC meeting). The ESCs noted the DCAR model had been amended to include the costs associated with BMD testing with changes also made to the modelled population characteristics to be consistent with the proposed population. The ESCs noted these changes increased the ICER from \$redacted per QALY in the November 2022 risedronic acid PBAC submission to \$146,477 per QALY (Addendum). The ESCs noted the number needed to test of 47 to identify an additional patient with osteoporosis based on this scenario, which was significantly higher than the estimate based on the November 2022 risedronic acid PBAC submission model that indicated the number needed to test was 7.

In addition, the ESCs recalled that the November 2022 risedronic acid submission to the PBAC assumed 100% persistence to risedronate EC and standard care treatments. The modelled extent of treatment benefit associated with early risedronate EC treatment was therefore reliant on continuing treatment for up to 20 years in patients without fracture (Table 8, risedronic acid PSD, November 2022 PBAC meeting). The ESCs recalled that the PBAC had previously considered the assumption of continuing treatment benefits to be of significant concern for osteoporosis medications given the less than ideal rates of persistence in practice (para 7.13, romosozumab PSD, November 2018 PBAC meeting). The ESCs noted that in addition to including the costs associated with BMD testing, the economic model in the DCAR and Addendum incorporated imperfect persistence estimates in sensitivity analyses. The ESCs noted that the treatment persistence estimates were derived from median durations of therapy from the DUSC review of denosumab, October 2020 report and considered the application of estimates from this source was appropriate. The ESCs noted that due to the limitations of the model structure it was only possible to apply persistence estimates to transitions from the no fracture state, with perfect persistence assumed for transitions from the new/prior fracture health states. The ESCs noted that assuming patients may initiate osteoporosis treatment more than once (as per the Addendum imperfect persistence scenarios) increased the base case ICER for risedronate EC (30 day dispensing) from \$146,447 per QALY gained to \$616,741 per QALY gained.

The ESCs considered that concerns raised by the PBAC in its consideration of the risedronic acid submission remain regarding the use of use of alendronate as a proxy to determine risedronate treatment effects and overestimating the cost of fractures occurring in the younger population. However, the ESCs noted the ICER in the DCAR was not overly sensitive to plausible variation in these inputs in sensitivity analyses. The ESCs also recalled potential issues associated with the estimation of utilities from a study in an older age group (average age of study participants was 72 years of age) with it unclear whether these estimates were applicable to a younger population without prior fracture, who may experience less severe consequences after fracture (para 6.64, risedronic acid PSD, November 2022 PBAC meeting). The ESCs considered a long time horizon magnifies concerns raised regarding the estimation of utilities.

The ESCs noted that in addition to including the costs associated with BMD testing, a reduction in the time horizon from 20 years to 10 years was included in the sensitivity analyses presented in the Addendum. The ESC noted that a 10 year time horizon increased the ICER for risedronate EC (30 day dispensing) from \$146,447 per QALY gained to \$334,940 per QALY gained. The ESCs considered that a time horizon of greater than 10 years may be clinically appropriate for the proposed population. However, the ESCs advised that because of the inflexibility of the model structure to appropriately model treatment persistence a 10-year time horizon was preferred as a more conservative specification.

The ESCs advised that the respecified base case relevant for decision making was the expansion of BMD testing to those of 65-69 years of age with no repeat BMD testing with a 10 year time horizon and imperfect persistence assumed. However, the ESCs noted that the number needed to test to identify an additional patient with osteoporosis, the number needed to treat to prevent

any fracture and as a consequence the ICERs are high for all modelled drug scenarios (ICER range: \$262,259 - \$399,169 per QALY gained), and ICERs of this magnitude are not typically considered by MSAC and PBAC to represent acceptable cost-effectiveness.

The ESCs noted the new financial models presented in the Addendum as per the request from the MSAC ESC February 2024 meeting. Regarding the methodology used for the updated financial analyses, the ESCs noted that there was no potential to further separate the utilisation data for initial and repeat testing because the utilisation estimates in the younger population were derived from utilisation data from the 70–74-year-old age band, inclusive of 1 initial test using the 5-year testing item and a maximum of 2 repeats using the 2-year testing item. The ESCs noted that utilisation of MBS items 12315 and 12321 were excluded once the population reached the existing age criteria of 70 years, as this represents the current real-world access to BMD testing. The ESCs considered that the utilisation of these two MBS items would already impact the utilisation of the 2- and 5-year testing items in the 70–74-year-old age group, which was used as the basis for modelled projections. The ESCs noted the implicit assumption that the utilisation of these MBS items would be broadly similar between the 60–69-year-old age band and the 70–74-year-old age band. However, the ESCs considered that the real-world utilisation for these two age bands may in fact differ significantly and identified this as a limitation to the financials model.

The ESCs noted the budget impact is predominately raised by the cost to the MBS as opposed to the drug cost for osteoporosis treatment. The ESCs considered this is evident due to the significant cost(s) associated with BMD testing, when compared to the small incremental drug cost that is offset by reduced fractures and management costs. The ESCs noted the scenario presented in the Addendum for the Risedronate EC 35mg weekly – 30-day dispensing included a revised budget impact of \$134,505,759 to the MBS and \$48,607,326 to the PBS over six years. The ESCs noted that in the 65-69 age band for the Risedronate EC model, the budget impact over 6 years resulted in a \$51,022,041 increase to the MBS; and a \$22,701,137 cost to the PBS. The ESCs noted the zoledronic acid 5mg annual injection model for the 65-69 age band produced a similar cost of \$58,575,307 to the MBS; and a substantial reduction in the cost to the PBS at \$5,609,352. The ESCs noted that the MBS budget cost is constant across all drug related scenarios, except for the Zoledronic acid which is attributed to infusion cost(s). The ESCs noted that MBS items for initiating treatment could occur under a range of MBS items for GP or specialist visits rather than item 104 used to model the administration costs, however the ESCs considered that variation in this model input would have negligible impact to the modelled results. Consistent with the results of the economic analysis, the ESCs noted that the alternative scenario based on the 65-69 age band with no repeat testing yielded lower financial impacts to the MBS and PBS/ Repatriation Pharmaceutical Benefits Scheme (RPBS).

The ESCs noted that the overall expenditure on existing DEXA MBS items increased by 19.5% from FY2021-22 to FY2022-23, with approximately 100,000 additional services performed in the 2022-23 financial year, compared to the previous financial year. Additionally, the ESCs noted the expenditure on MBS items 12320 and 12322 increased by 29.3% from FY2021-22 to FY2022-23, with approximately 60,000 additional services performed in the 2022-23 financial year, compared to the previous financial year. The ESCs noted that the growth in utilisation of BMD testing – in particular for DEXA scans – is significant and one of the fastest growing diagnostic imaging services listed on the MBS. The ESCs considered that the real-world growth in the 60-69 age band meant that financial estimates could be larger than the estimated, due to the significant growth in the sector.

The ESCs noted the Pre-Sub-Committee Response (PSCR) from the sponsor of risedronate EC which highlighted recommendations from the 2024 RACGP and Healthy Bones Australia guidelines and presented on the characteristics of the risedronate EC formulation.

The ESCs noted and welcomed consultation input from 5 professional organisations and 1 consumer organisation. As previously noted by the MSAC ESC in February 2024, there was mixed support for expanding the MBS items 13230 and 12322 to people aged 60-69 years. Feedback supporting lowering the age to include the 60-69 age group cited an increased risk of fracture in that age group. The ESCs noted a concern with regards to cumulative radiation experienced by patients having DEXA scans, however considered the dose associated with DEXA is very low and so considered that it did not represent a significant safety concern. The ESCs noted the consultation feedback received from the Queensland Aboriginal and Islander Health Council (QAIHC) highlighted that Aboriginal and Torres Strait Islander people have a substantially greater fracture risk than non-Indigenous Australians. The QAIHC highlighted minimal trauma hip fractures were reported in 52% of First Nations people aged 40-74 years in an epidemiological study compared with 19% of non-Indigenous people.

The ESCs noted that the Royal College of General Practitioners (RACGP) recommended that the MBS item follow evidence-based recommendations as outlined in the revised guidelines:

- Osteoporosis management and fracture prevention in postmenopausal women and men over 50 years of age (RACGP and Healthy Bones Australia; released in March 2024)⁸
- RACGP Guidelines for preventive activities in general practice 9th edition (Red Book⁹).

The ESCs noted that the RACGP guidelines recommend the use of an online calculator/tool, termed the Fracture Risk Assessment Tool (FRAX) to check for fracture risk in people aged ≥ 50 years with non-modifiable/lifestyle risk factors (and no fracture). These patients would be referred for a DEXA BMD if the FRAX calculator indicated a major osteoporotic fracture (MOF) risk of $\geq 10\%$. If MOF is $< 10\%$ the RACGP guidelines state that DEXA BMD is not recommended. The ESCs noted that the FRAX calculator can utilise a BMD score – however, does not require one to be entered to generate a result. The ESCs noted the RACGP guidelines do not recommend screening for osteoporosis with BMD measurement in the general population and also do not recommend routinely doing repeat BMD + FRAX within 2 years except in special circumstances.

The ESCs also noted that the guidelines contain no specific recommendation(s) on First Nations people. The ESCs considered that BMD testing should be used more broadly in First Nations people, given the high prevalence for a substantially increased risk of fractures in these populations.

In addition, the ESCs noted the importance of resistance training and exercise in the prevention of osteoporosis. The ESCs considered patients are much more likely to consider commencing an exercise program after experiencing a fall. The ESCs considered that increased uptake of preventative health care programs is optimal and that perhaps risk assessments – such as FRAX – coupled with exercise programs would be a beneficial alternative to BMD scans.

The ESCs queried whether alternative subpopulations, such as high-risk groups and First Nations people who otherwise do not have subsidised access to BMD testing on the MBS may be more likely to benefit from an expansion of these services than the proposed age-based expansion of BMD testing services to 60-69 years on the MBS, which yielded high ICERs ($> \$500,000$ per QALY gained) across all modelled drug scenarios. Thus, the ESCs discussed the following clinical scenarios for expanded BMD testing:

⁸ <https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/osteoporosis/executive-summary>

⁹ <https://www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Guidelines/Red%20Book/Guidelines-for-preventive-activities-in-general-practice.pdf>

- 1- Expansion of BMD testing to all people aged 65-69 with no repeat testing (respecified base case).
- 2- Expansion of BMD testing to high-risk groups and First Nations people aged 65-69 with no repeat testing.

The ESCs considered that the introduction of the FRAX calculator would likely be beneficial for both scenarios whereby those with a MOF risk of $\geq 10\%$ are referred for a BMD testing.

Overall, the ESCs considered that given that the number needed to test to identify an additional patient with osteoporosis would likely reduce in more targeted risk-based populations (using the FRAX tool) – which would likely improve cost-effectiveness and with more modest cost implications, that the alternative subpopulations most likely to benefit from an expansion of BMD testing for MSAC and PBAC consideration should be the high-risk groups and First Nations people in the 65-69 age band. However, the ESCs noted that these subpopulations were not modelled in the economic and financial evaluation. Due to the slow nature of BMD changes on DEXA scans, the ESCs considered that the value of repeat testing is also limited in these subpopulations.

13. Applicant comments on MSAC's Public Summary Document

The Department of Health and Aged Care (the department) would like to acknowledge the contribution of the Dubbo Osteoporosis Epidemiology Study (DOES) and their provision of invaluable clinical data that was used for the purposes of informing the MSAC consideration. However, the department notes that the DOES authors were not involved in the MSAC process beyond the provision of the original clinical data. Interpretation of the MSAC consideration should therefore be limited to seeking to understand the basis for the MSAC outcome and not used in conjunction with the DOES clinical study.

14. Further information on MSAC

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

Appendix

MSAC ESC – February 2024

MSAC ESC noted that the Medical Services Advisory Committee (MSAC) Executive requested the Department of Health and Aged Care to undertake a fit-for-purpose assessment of bone mineral density (BMD) testing in individuals aged 60–69 years. The aim is to assess the economic and financial implications associated with amending the current age restriction for MBS items 12320 and 12322 from age 70 years and above to age 60 years and above, to align with proposals to amend the age restriction for Pharmaceutical Benefits Scheme (PBS)-listed osteoporosis medicines for primary prevention of fractures.

MSAC ESC noted that the Pharmaceutical Benefits Advisory Committee (PBAC) had considered:

- expanding the current age range for PBS-listed osteoporosis medications for primary prevention of fractures to those under 70 years of age (see PBAC outcome for Osteoporosis Therapy Restrictions Review, September 2021 PBAC meeting¹⁰).
- expanding the age restriction for risedronic acid (risedronate) to include patients aged 60 to 69 years (see Public Summary Document [PSD] for risedronic acid, November 2022 PBAC meeting with March 2023 Addendum¹¹).

In both instances, the PBAC was of a mind to support these changes but deferred making a recommendation regarding expanding the age restriction for PBS-listed osteoporosis medications pending a review of the MBS implications, to ensure that the MBS items for bone densitometry could be aligned with the PBAC recommendations. However, MSAC ESC noted that the PBAC had multiple concerns with the risedronate economic model and considered it may not be reliable for decision making. Based on advice that the sponsor for the risedronic acid PBAC submission would not pursue a codependent submission to assess the MBS implications, the PBAC subsequently updated their advice to not recommend the risedronic acid (risedronate) submission, noting the MSAC Executive advice that the department would independently progress the PBAC advice from the Osteoporosis Therapy Restrictions Review in September 2021.

MSAC ESC noted that during the MBS Review Taskforce's review, two time-restricted MBS items were introduced for BMD testing for people aged 70 years and above (MBS items 12320 and 12322) to replace existing MBS item 12323, which was not time-restricted. Individuals aged 70 years or over would continue to be eligible for an initial test using MBS item 12320. Individuals with a BMD T-score of –1.5 or above would be eligible for repeat testing every five years, and individuals with a BMD T-score less than –1.5 and above –2.5 would be eligible for repeat testing every two years.

MSAC ESC noted that although the current application focussed on amending MBS items 12320 and 12322, there are other MBS items available that facilitate conditional access to bone densitometry (dual energy Xray [DEXA] only) for patients with minimal trauma fracture (MBS item 12306), conditions associated with more rapid bone loss (MBS items 12312 and 12315) and monitoring of patients after a significant change in therapy (MBS item 12321). MSAC ESC also noted that MBS items 12312 and 12315 are not age restricted and therefore, some of the

¹⁰ <https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2021-09/September-2021-pbac-web-outcomes.pdf>

¹¹ <https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2022-11/files/risedronic-acid-psd-11-2022-03-2023.docx>

proposed population who may have a specific condition known to increase bone loss may already be receiving BMD testing via these items.

MSAC ESC noted and welcomed consultation input from 4 professional organisations and 1 consumer organisation. MSAC ESC noted that the consumer feedback provided mixed support for the application. MSAC ESC noted from feedback provided by the Royal College of General Practitioners (RACGP) that per RACGP's guidelines for Osteoporosis prevention, diagnosis and management in postmenopausal women and men over 50 years of age, GPs are already assessing osteoporosis risk in the proposed population. MSAC ESC noted the RACGP stated that this guideline directed case-finding process used by GPs avoids the potential patient harms of over-screening and ensure there is access for those who need it. However, MSAC ESC noted other feedback supported lowering the age to include the 60–69 age group, citing an increased risk of fracture in that age group. MSAC ESC also noted several consultation inputs raised matters around radiation safety/dose of quantitative computed tomography (QCT) versus DEXA for assessing bone densitometry in the proposed MBS items.

MSAC ESC noted that consistent with the MSAC Executive advice, a clinical evaluation was not conducted for this fit-for-purpose department-contracted assessment report.

MSAC ESC noted that the economic evaluation was a two-part analysis based on a cost-effectiveness analysis (CEA) of universal BMD testing versus no BMD testing in individuals aged 60–69 years (Part A), linked to a separate cost-utility analysis (CUA) of early versus delayed osteoporosis treatment (Parts A & B). The results from Part A were presented as the main analysis that provided an estimated upfront testing cost (including repeat testing) per additional patient diagnosed with osteoporosis, defined by either BMD criteria or fracture. A supplementary analysis that applied the results of Part A as additional costs at entry of patients into the Part B CUA model assessed the cost-effectiveness of early initiation of osteoporosis treatment (detected via BMD testing) in patients aged 60–69 years without fracture versus delayed treatment of patients who have a fracture or reach age 70 years. MSAC ESC noted that while both the CEA (Part A) and CUA (Parts A & B) are relevant for informing MSAC's advice, MSAC ESC advised that the CUA which linked test results to health outcomes and estimated the incremental cost per quality adjusted life year (QALY) gained is likely more informative for decision making than the CEA that estimated the incremental cost per additional osteoporosis diagnosis.

MSAC ESC noted that the comparator for Part A of the economic analysis was standard care (i.e. no testing and standard medical management), including age-appropriate general lifestyle and bone health advice (e.g. exercise, sunshine, diet, calcium and vitamin D supplements when required).

Regarding cost-effectiveness of BMD test versus no testing (Part A CEA), MSAC ESC noted that the structure of the economic evaluation was based on a Markov microsimulation, consistent with published economic evaluations identified in the literature review. However, a bespoke structure was required, to model patient trajectories according to BMD T-score categories that determined eligibility for repeat testing as per the proposed MBS items. MSAC ESC noted that there was no published data regarding rate of decline using BMD T-score categories so an *ad hoc* analysis was conducted of epidemiological data from the Dubbo Osteoporosis Epidemiology Study (DOES).

MSAC ESC noted that the assumptions of 100% test uptake and 100% test accuracy are unlikely to be applicable to clinical practice. However, there were no available data to reliably estimate initial and repeat testing rates or test accuracy in the eligible population without fracture or rapid bone loss conditions. Consequently, MSAC ESC agreed the results should be considered the most optimistic estimate of upfront costs based on the incremental cost per additional patient diagnosed with osteoporosis.

MSAC ESC noted that the model also assumed that BMD testing does not have any impact on standard care. For example, having detected osteopenia was assumed to have no impact on use of calcium and vitamin D supplements or non-pharmacological interventions such as exercise or smoking cessation. MSAC ESC noted that there are known benefits associated with these interventions in terms of fracture prevention that were not captured in this analysis.

MSAC ESC noted that the CEA results indicate that BMD testing versus no BMD testing, in patients aged 60–69 years without fracture or conditions associated with rapid bone loss, is associated with an incremental cost of \$4,673 per additional patient diagnosed with osteoporosis.

MSAC ESC noted that based on the modelling, the number needed to test to identify an additional patient with osteoporosis was 47 (calculated as the undiscounted incremental cost per additional patient diagnosed with osteoporosis, \$5,278, divided by the MBS cost per BMD test of \$112.15). This estimate was considerably higher than previously noted by the MSAC Executive based on prevalence data presented in the November 2022 risedronic acid submission (approximate number needed to test of 7 using a rough osteoporosis prevalence of 14.3% weighted by gender in 60–69-year-olds assuming one test per person). The number needed to test in the economic evaluation is based on lower prevalence estimates from the Dubbo Osteoporosis Epidemiology Study (DOES) analysis in individuals without fracture (between **Redacted%** and **Redacted%**, weighted by gender in 60–69-year-olds) but also included the impact of repeat testing.

MSAC ESC noted the incremental cost in the CEA was driven by costs associated with BMD testing, with no other costs included in the base case. A greater proportion of the incremental cost was associated with repeat testing, particularly 2-yearly repeat testing. MSAC ESC questioned the value of repeat testing in this cohort given the low numbers of additional patients with osteoporosis detected via BMD testing beyond the initial test at baseline.

MSAC ESC noted the difference in health outcomes was driven by the increased proportion of patients diagnosed with osteoporosis through BMD testing. The proportion of patients with undiagnosed osteoporosis in the BMD test arm was relatively small given the assumption of 100% test uptake and 100% test accuracy.

MSAC ESC noted that the Part A CEA was most sensitive to alternative testing intervals and the time horizon. The scenario analyses using an older age band (65–69 years) and alternative testing intervals indicated improved cost-effectiveness when the age threshold is increased to 65 years, particularly when testing is based on a single test at the qualifying age only.

Regarding the cost-effectiveness of early versus delayed treatment of osteoporosis (Part A & B supplementary analysis), MSAC ESC noted that the economic model was based on the model presented in the November 2022 risedronic acid submission to the PBAC. ESC noted that the PBAC previously considered the risedronic acid economic model to be problematic and that it may not be reliable for decision making due to multiple concerns with assumptions and inputs, as well as the lack of BMD testing costs. MSAC ESC noted most (but not all) of the issues with the risedronic acid economic model appeared to have been addressed in this assessment.

MSAC ESC noted that the previous PBAC risedronic acid submission's economic evaluation was based on early initiation of treatment with risedronic acid in patients aged less than 70 years with a BMD T-score of –2.5 or less, who are without fracture, versus delayed treatment with standard care therapies (predominantly denosumab) in patients who fracture or reach the age of 70 years. The modelled population was synthesised using epidemiological data, with fracture risks estimated using the Garvan risk calculator, treatment effects derived from subgroups of the alendronate (FIT-CFA) and denosumab (FREEDOM) placebo-controlled trials as well as other modelled variables. ESC noted the Garvan validation studies (based on DOES cohort started in 1989) may not reflect contemporary fracture risks and standards of care. In addition, MSAC ESC

noted that the Garvan study included a mixed cohort of primary and secondary prevention compared with the proposed primary prevention population. However, MSAC ESC noted the osteoporosis incidence rates by gender and T-score predicted in the Part A model are consistent with published estimates from the DOES study¹².

MSAC ESC noted that key differences with the November 2022 risedronic acid PBAC submission were the inclusion of the costs associated with BMD testing to identify patients with osteoporosis eligible for treatment, and amendment of the modelled population characteristics to be consistent with the proposed population.

MSAC ESC noted that the modelled cost-effectiveness of early vs delayed osteoporosis treatments (Part A & B supplementary analysis) indicated that, early initiation of risedronic acid treatment was associated with an incremental cost effectiveness ratio (ICER) of \$146,387 per QALY gained compared to delayed initiation of treatment with standard care for osteoporosis in patients aged 60–69 years. MSAC ESC considered that this estimate should be considered optimistic, given the model base case assumed perfect treatment persistence over the 20-year time horizon, included upfront BMD testing costs assuming 100% uptake and 100% accuracy, and assumed 100% treatment uptake in patients diagnosed with osteoporosis. This compared to an ICER of \$redacted per QALY gained in the November 2022 risedronic acid PBAC submission, which did not include the costs of BMD testing to identify patients with osteoporosis; included a younger population (62 versus 65 years), with a smaller proportion of males (15% versus 29%); and was based on a higher price of risedronic acid (Dispensed Price for Maximum Quantity of \$36.09 in April 2022 compared with \$33.41 in October 2023). Given the substantial change in the modelled cost-effectiveness of risedronate for people aged 60–69 years, and the likely impact on the PBAC's previous advice, MSAC ESC advised that there may be value in seeking input from the PBAC Economics Sub Committee (ESC) to ensure that the revisions to the risedronate model are a reasonable reflection of the previous advice from that subcommittee. In particular, to ask whether the PBAC ESC is of the view that the base case analysis should instead have a time horizon of 10 years (not 20 years) and/or should include imperfect (not perfect) persistence/adherence to osteoporosis medications. MSAC ESC noted the results from sensitivity analyses showed that the ICER was highly sensitive to variations in each of these assumptions (see Table 11).

MSAC ESC queried whether a 20-year time horizon was suitable, given that everyone in the 60–69-year-old cohort will be eligible for testing within less than 10 years (i.e. when they turn 70) and noting that PBAC ESC had advised the risedronic acid economic evaluation should have been revised to have a 10 year time horizon.

MSAC ESC noted that the incremental cost was driven by the costs associated with BMD testing to identify patients with osteoporosis. Scenario analyses using alternative BMD testing scenarios and/or limiting the population to patients aged 65 to 69 years resulted in more favourable ICERs (consistent with the results of the Part A economic analysis).

MSAC ESC noted that, based on the model output, the number needed to treat (NNT) to prevent any fracture was 39, the NNT to prevent a hip fracture was 97, and to prevent a non-hip fracture was 65. These estimates were considerably higher than the NNTs reported in the November 2022 risedronic acid submission (NNT to prevent any fracture 20; hip fracture 57; non-hip fracture 31) due to differences in patient characteristics (mean age 65 years and 29% male in the current model, compared with a mean age of 62 years and 15% male in the November 2022 risedronic acid PBAC submission).

¹² Jones, G., Nguyen, T. V., Sambrook, P. N., Kelly, P. J., Gilbert, C., & Eisman, J. A. (1994). Symptomatic Fracture Incidence in Elderly Men and Women: The Duboo Osteoporosis Epidemiology Study (DOES). *Osteoporos Int*, 4, 277-282.

MSAC ESC noted that an epidemiological approach was used to estimate the extent of use and financial implications of extending BMD testing to individuals aged 60–69 years under the MBS.

MSAC ESC noted that there were insufficient contemporary Australian data to inform a detailed epidemiology-based model on expected utilisation. Therefore, a simplified approach was taken by extrapolating testing rates in the existing population (individuals aged 70 years or older) and applying these estimates to the target population (individuals aged 60–69 years). Testing rates in the existing population were estimated based on Australian Bureau of Statistics data on the size of the Australian population by age and gender in 2018–2022. These estimates were then compared with MBS data on the age and gender of individuals using BMD scanning items (MBS 12320, MBS 12322) over the same time period.

MSAC ESC noted that expanding the population eligible for BMD testing would increase the annual number of scans conducted from 230,771 in Year 1 to 239,028 in Year 6. For comparison, the total number of BMD scans conducted in 2022 for the existing population aged 70 years or older was 249,996.

MSAC ESC noted that the estimated net cost to the MBS for extending BMD testing to a younger population was \$22.0 million in Year 1, increasing to \$22.8 million in Year 6, with a cumulative total of \$134.5 million over 6 years.

MSAC ESC noted the uncertainty associated with the estimated budget impact of expanded BMD testing was explored in sensitivity analyses, which indicated that the budget impact estimate was most sensitive to the uptake rate of BMD testing over time, and the age band eligible for testing.

To address some outstanding uncertainties, MSAC ESC requested the following additional work for the assessment to subsequently be jointly considered by the PBAC/MSAC ESCs:

- MSAC ESC advised a summary table of ICERs and budget impact analyses to be completed by the assessment group to inform MSAC advice on expanding MBS items 12320 and 12322, and the PBAC's reconsideration of its deferred advice from the Osteoporosis Therapy Restrictions Review in September 2021.
 - The ICERs in the requested summary table to be presented for the base case (20 year time horizon and assumption of perfect persistence to treatment); and additionally presented for an alternative base case with a time horizon of 10 years as preferred by PBAC ESC (para 6.54 risedronic acid PSD) AND/OR assuming imperfect treatment persistence/adherence patterns.
 - The budget impact analyses in the requested summary table could include an additional column presenting the financial impacts to the PBS.
- MSAC ESC requested further clarification regarding methodology used for the financial analyses, including:
 - whether it could be separated for repeat testing at 2 and 5 year intervals which would improve transparency of the modelling of initial and repeat testing
 - whether utilisation of MBS items 12315, 12321 (by respective age groups) needed to be accounted for (i.e. excluded) in the utilisation estimates as some patients in the proposed expanded population may be able to already access BMD testing under these items.
- MSAC ESC requested the department provide further information on the ICERs and financial estimates that informed past MSAC advice for Applications 1162, 1313, and 1665 as a potential frame of reference for MSAC consideration.