Australian Government

Department of Health

Application 1665

Radiofrequency Echographic Multi Spectrometry for bone density measurement & determination of osteopenia/osteoporosis

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Email: hta@health.gov.au
Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant): Cortex Health Pty Ltd
Corporation name: Cortex Health Pty Ltd
ABN: 17 144 062 386
Business trading name: Cortex Health Pty Ltd

Primary contact name: REDACTED

Primary contact numbers
Business: **REDACTED**
Mobile: **REDACTED**
Email: **REDACTED**

Alternative contact name: REDACTED

Alternative contact numbers
Business: **REDACTED**
Mobile: **REDACTED**
Email: **REDACTED**

2. (a) Are you a lobbyist acting on behalf of an Applicant?

☐ Yes
☒ No

(b) If yes, are you listed on the Register of Lobbyists?

☐ Yes
☐ No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Radiofrequency echographic multi spectrometry for bone density measurement & determination of osteopenia/osteoporosis.

4. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

The Echolight system can accurately measure low bone mineral density (BMD) at all levels. Of note low BMD is present in osteopenia and osteoporosis. Osteoporosis is a condition where bones become thin, weak and fragile, such that even a minor bump or accident can cause a broken bone (minimal trauma fracture). Examples of such events might include falling out of a bed or chair, or tripping and falling while walking. Osteopenia is a condition when bone mineral density is lower than normal but not low enough to be classified as osteoporosis. Fractures due to osteoporosis can result in chronic pain, disability, loss of independence and premature death. Osteoporosis has significant morbidity and mortality, with 93,321 hospitalisations for minimal trauma fractures in people aged 50 and over and 6,838 hospitalisations for osteoporosis for people aged 50 and over reported in Australia in 2017–18. Osteoporosis is often undiagnosed, but largely a preventable disease once diagnosed and treated.

5. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

Echolight is a unique, non-invasive ultrasound device for bone characterisation and micro architecture assessment through scanning of central reference sites (lumbar vertebrae and proximal femur). Echolight technology is based on the new REMS (i.e. Radiofrequency Echographic Multi Spectrometry) method, an innovative ultrasound approach to the diagnosis of osteoporosis, which integrally exploits all the spectral features of the " radiofrequency (signals acquired during an echographic scan) of the target anatomical site to determine the status of internal bone architecture.

Echolight is a software-assisted, non-invasive echographic scan for evaluation of BMD at the lumbar vertebrae (L1-L4) and the femoral neck providing all the standard parameters for the diagnosis of osteoporosis, i.e. BMD, T-score, Z-score. The technology does not require radiological protection and is portable. Minimal training of operators is required, with high reproducibility of results observed.

6. (a) Is this a request for MBS funding?

☒ Yes
☐ No

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

☐ Amendment to existing MBS item(s)
☒ New MBS item(s)

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

N/A

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

N/A

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

i. ☐ A new item which also seeks to allow access to the MBS for a specific health practitioner group
ii. ☒ A new item that is proposing a way of clinically delivering a service that is new to the MBS
iii. ☐ A new item for a specific single consultation item

(f) Is the proposed service seeking public funding other than the MBS?

☐ Yes
☒ No

(g) If yes, please advise:

N/A

7. What is the type of service:

☐ Therapeutic medical service
☒ Investigative medical service
☐ Single consultation medical service
☐ Global consultation medical service
☐ Allied health service
☐ Co-dependent technology
☐ Hybrid health technology

8. For investigative services, advise the specific purpose of performing the service *(which could be one or more of the following)*:

i. ☐ To be used as a screening tool in asymptomatic populations
ii. ☒ Assists in establishing a diagnosis in symptomatic patients
iii. ☒ Provides information about prognosis
iv. ☐ Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
v. ☒ Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

9. Does your service rely on another medical product to achieve or to enhance its intended effect?

☐ Pharmaceutical / Biological
☐ Prosthesis or device
☒ No

10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

N/A

(b) If yes, please list the relevant PBS item code(s):

N/A

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

N/A

(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?

N/A

11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?

☐ Yes
☐ No

(b) If yes, please provide the following information (where relevant):

N/A

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?

☐ Yes
☐ No

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?

☐ Yes
☒ No

There are ARTG registered "ultrasound system, bone absorptiometer" devices registered, however these devices are not comparable. These devices are only qualitative (giving a green / yellow/ red indicator), used at proximal sites (wrist & heel), are rarely used in Australia and are not comparable to Echolight in that they cannot be used to measure BMD, T-Score, Z-score at the reference sites (proximal femur and lumbar spine).

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):

N/A

12. Please identify any single and / or multi-use consumables delivered as part of the service?

Single use consumables: N/A
Multi-use consumables: Ultrasound gel

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

13. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:

N/A

(b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

☐ Class III
☐ AIMD
☒ N/A

14. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

☐ Yes (If yes, please provide supporting documentation as an attachment to this application form)
☒ No

(b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

☒ Yes (if yes, please provide details below)
☐ No

ARTG listing, registration or inclusion number: 344830

TGA approved indication(s), if applicable: Not applicable

TGA approved purpose(s), if applicable: Echolight devices (EchoStation, EchoS, EchoHybrid) are all designed to accurately measure bone mineral density (BMD). These devices use patented Radiofrequency Echographic Multi Spectrometry (REMS), highly specific ultrasound technology. The intended use is as a screening &/or diagnostic tool to determine BMD and give the clinician a T-Score and Z-score. The generated findings & report will determine whether the patient has normal BMD or has any degree of osteopenia or osteoporosis according to their specific readings vs matched age controls.

15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

N/A

16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?

N/A

PART 4 – SUMMARY OF EVIDENCE

An overview of the available evidence is provided (literature search undertaken March 2021). This data will be updated, as required, following an extensive literature search in the application submission. There are a number of large comparative studies where patients underwent both DXA and REMS (Echolight) scans, with efficacy results reported. The 3 largest comparative studies were D Paola et al. (2018) in N=1914, Adami et al. (2020) with N=1,516 (with 5-year follow-up) and Cortet et al. (2021) in N=4,307 patients, providing extensive directly comparative clinical evidence of the effectiveness of REMS technology in the diagnosis in 'at risk' population. The studies are listed in alphabetical order (first author) with comparative studies presented first, followed by studies that used Echolight/REMS in a relevant population but did not compare with DXA scans.

Cortet et al. (2021) included reports results for the full population of women at risk of developing osteoporosis, including a subgroup of patients ≥70 years, one of the proposed populations. Both Cortet et al. 2021 and Adami et al. 2021 include patients who had experienced a fragility fracture, consistent with the proposed population requiring review more than 12 months after a fragility fracture.

Tomai et al. (2020) compared REMS with DXA in patients with rheumatologic diseases, including rheumatoid arthritis, with results showing that REMS technology can be a diagnostic option especially in patients with rheumatologic diseases that cause alterations in the spine reducing the diagnostic sensitivity of DXA technology. Patients with rheumatoid arthritis with risk factors for osteoporosis are a proposed population for listing.

Bojinca et al. 2019 compared REMS technology in patients with and without rheumatoid arthritis at risk of osteoporosis, providing additional clinical data in a proposed population.

Overall, the studies provided directly comparative evidence for effectiveness of REMS versus the comparator in diagnosis at risk groups, including in proposed populations such as those aged ≥70 years, at risk due to rheumatoid arthritis and in patients who have experienced minimal trauma fractures.

17. **Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only).** ***Please do not attach full text articles, this is just intended to be a summary.***

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
Clinical studies comparing REMS (Echolight) with DXA scanning					
1.	Prospective observational cohort comparison of REMS and DXA scans.	Adami G, Arioli G, Bianchi G et al. (2020) Radiofrequency echographic multi spectrometry for the prediction of incident fragility fractures: A 5-year follow-up study. Bone 134: 115297	N=1,516. REMS T-score (for vertebral site, −2.9 [−3.6 to −1.9] in Group Fracture (F)', −2.2 [−2.9 to −1.2] in Group No fracture (NF)') and DXA T-score (−2.8 [−3.3 to −1.9] in Group F', −2.2 [−2.9 to −1.4] in Group NF') were statistically significant (p-value<0.001). Analogous results were obtained for femoral neck. Using T-score cut-off of −2.5, REMS identified Group F' patients with a sensitivity of 65.1% and specificity of 57.7% of (OR = 2.6, 95%CI: 1.77–3.76, p < 0.001), whereas DXA showed a sensitivity of 57.1% and a specificity of 56.3% (OR = 1.7, 95%CI: 1.20–2.51, p-value = 0.0032)	https://pubmed.ncbi.nlm.nih.gov/32092480/	May 2020
2.	See Adami 2020	Adami G, Arioli G, Bianchi G et al (2019) Prediction of incident fragility fractures through radiofrequency echographic multi spectrometry (REMS). Ann Rheum Dis 78(Suppl 2):933.	Abstract publication of Adami 2020.	https://ard.bmj.com/content/78/Suppl_2/933.2	2019 Abstract/poster publication See Adami 2020 for full study publication

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
3.	Prospective observational cohort comparison of REMS and DXA scans.	Amorim D, Sakane E, Maeda S et al. (2020). P-519 New technology REMS demonstrated good accuracy for the diagnosis of osteoporosis defined by DXA , in Brazilian adult women. American Society for Bone and Mineral Research (ASBMR) Annual Meeting 2020	N=343. In 227 spines and 238 femurs in comparison high correlation between both methodologies BMD values (r=0.75, p<0.00) for lumbar spine and r=0.78 p<0.001 for femoral neck). Average difference between REMS and DXA outcomes (expressed as bias ± 1.96 SD) was -0.026 ± -0.1758 g/cm^2 for spine and -0.027 ± -0.1525 g/cm^2 for neck. REMS discriminated between osteoporotic and non-osteoporotic women for both lumbar spine (sensitivity 84%, specificity 94.6%) an femoral neck (sensitivity 92.6%, specificity 93.5%).	https://www.echolightmedical.com/wp-content/uploads/2020/10/ASBMR2020-P-519-New-technology-REMS-demonstrated-good-accuracy-for-the-diagnosis-of-osteoporosis-defined-by-DXA-in-Brazilian-adult-women..pdf	September 2020
4.	Prospective observational cohort comparison to assess diagnostic accuracy of REMS vs. DXA.	Casciaro S, Peccarisi M, Pisani P (2016). An Advanced Quantitative Echosound Methodology for Femoral Neck Densitometry. Ultrasound Med Biol. Jun;42(6):1337-56.	N=377 female, proximal femur scan. Assuming DXA as reference, the accuracy of REMS based diagnoses resulted 94.7%, with k=0.898 (p <0.0001). Significant correlations were also found between REMS estimated bone mineral density and corresponding DXA values, with r^2 up to 0.79 and root mean square error 5.9–7.4%.	https://pubmed.ncbi.nlm.nih.gov/27033331/	June 2016

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
5.	Prospective observational cohort comparison of REMS and DXA scans.	F. Conversano, R. Franchini, A. Greco, et al. (2015) A novel ultrasound methodology for estimating spine mineral density, Ultrasound Med. Biol. 41 (1) 281–300,	N=342 females (aged 51-60 y). Versus DXA, the accuracy of REMS based diagnoses was 91.1%, with k= 0.859 ($p < 0.0001$). Significant correlations were also found with r^2 values up to 0.73 and a root mean square error of 6.3%-9.3%. The proposed method has the potential for future routine application in US-based diagnosis of osteoporosis.	https://www.umbjournal.org/article/S0301-5629(14)00569-9/fulltext	January 2015
6.	Prospective, multicentre observational cohort comparison to assess diagnostic efficacy of REMS and DXA scans, plus the ability to identify patients with previous osteoporotic fractures.	Cortet B, Dennison E, Diez-Perex A et al. (in press) Radiofrequency Echographic Multi Spectrometry (REMS) for the diagnosis of osteoporosis in a European multicenter clinical context. Bone 143: 115786	N=4307 women; 30-90 yr,. Subgroup ≥70 years reported. Femoral neck scans: linear correlation between the BMD values measured by DXA and REMS was very high - Pearson correlation coefficient r = 0.93 and corresponding coefficient of determination $r^2 = 0.86$. For the lumbar spine cases: Pearson correlation coefficient of 0.94 ($r^2 = 0.88$). Both DXA and REMS discriminated significantly between fractured and non-fractured patients based on T-score values.	https://www.sciencedirect.com/science/article/pii/S8756328220305743	2021

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
7.	Multicentre, cross-sectional observational cohort study to assess precision and diagnostic accuracy for REMS vs. DXA.	Di Paola M, Gatti D, Viapiana O et al (2018) Radiofrequency echographic multispectrometry compared with dual X-ray absorptiometry for osteoporosis diagnosis on lumbar spine and femoral neck. Osteoporos Int 30:391–402.	N=1914 postmenopausal women (some patients not included in analyses due to errors during REMS or DXA scanning process). There was good agreement between REMS and DXA: the average difference in BMD (bias ± 2SD) was −0.004 ± 0.088 g/cm^2 for spine and − 0.006 ± 0.076 g/cm^2 for femur; demonstrating. accuracy and precision for REMS in assessing fracture risk.	https://link.springer.com/article/10.1007/s00198-018-4686-3	2019
8.	Prospective observational cohort comparison of REMS and DXA scans.	M.D. Tomai Pitinca, C. Caffarelli, S. Gonnelli (2020). Use of REMS technology in patients with spine artifacts.: A new diagnostic opportunity. Presented at The International Society for Clinical Densitometry (ISCD) 2020.	N=86 females. BMD assessed by REMS showed lower values in the spine compared to DXA: BMD 0.772 ± 0.065 vs 1.067 ± 0.210; T-score -2.5 ± 0.6 vs 0.2 ± 1.8. The BMD and T-score values measured with REMS and DEXA at the femoral site were highly correlated (p <0.01).	https://www.echolightmedical.com/iscd-2020/	2020 Conference presentation/ abstract

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
9.	Prospective observational cohort	M.D. Tomai Pitinca, C. Caffarelli, S. Gonnelli (2020). P-529 REMS technology a new diagnostic approach in patients with spine artifacts. American Society for Bone and Mineral Research (ASBMR) Annual Meeting 2020	N=86 females Methodology and results as above in Tomai Pitinca et al. 2020 presented at ISCD.	https://www.echolightmedical.com/wp-content/uploads/2020/10/ASBMR2020-P-529-REMS-technology-a-new-diagnostic-approach-in-patients-with-spine-artifacts.pdf	2020 Conference Abstract. Same data as Tomai Pitinca ISCD 2020 presentation.
10	Cohort observational comparison of REMS vs. DXA.	M.D. Tomai Pitinca, C. Caffarelli, S. Gonnelli (2020). REMS technology applied to rheumatic diseases European Congress of Rheumatology (EULAR) 2020	N=20 females patients. 18 lumbar and 20 femoral exams (DEXA vs REMS) were compared. Exams performed show a good diagnostic match (>60%LS and >85% FEMORE). The tests that didn't show diagnostic concordance were those affected by arthrosis processes (greater on the Spine). The REMS T-score values were lower than those obtained with the DXA method.	https://www.echolight.it/wp-content/uploads/2020/10/REMS-Technology-applied-to-rheumatic-diseases-EULAR2020.pdf	2020

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
Non-comparative Echolight studies (i.e. no comparison of REMS vs. DXA scanning; other clinical comparisons are reported)					
11	Prospective cohort study using REMS to measure BMD in rheumatoid arthritis (RA) and non-RA controls.	Bojinca V, Popescu C, Decianu R et al. (2019). A novel quantitative method for estimating bone mineral density using B-mode ultrasound and radiofrequency signals-a pilot study on patients with rheumatoid arthritis. Experimental and Therapeutic Medicine. 18(3)P:1661-1668. DOI: 10.3892/etm.2019.7746	N=106 with RA, N=119 controls. RA patients had a significantly lower spine and hip BMD, higher fracture risk and higher prevalence of osteoporosis. Compared to RA patients without osteoporosis, those with osteoporosis were significantly older and had a longer menopause duration, but they had a significantly lower BMI, body fat, BMR and prevalence of obesity.	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6676208/	September 2019

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
12	Observational cohorts to assess the influence of the variation 1) in patient position, 2) operator (both intra- and inter-) and 3) device on the REMS performance at lumbar spine and femoral neck.	Caffarelli C, Adami G, Arioli G. Influence of the variation of the operator, patient position and device on the measurement performance of radiofrequency echographic multi spectrometry (REMS) (2020). Ann Rheum Dis 1830 AB1082.	N=210, divided in to 7 groups of 30. The percentage coefficient of variation (CV%) with 95% CI and least significant change for a 95% confidence level (LSC). For lumbar spine • intra-operator repeatability CV%=0.37% (95%CI: 0.26%-0.48%), LSC=1.02%, • inter-operator repeatability CV%=0.55% (95% CI: 0.42%-0.68%), LSC=1.52% • inter-device repeatability CV%=0.53% (95% CI: 0.40%-0.66%), LSC=1.47%. Similarly low CV% and LSC values reported for femoral neck outcomes with all comparison sets. REMS densitometry is highly precise for both anatomical sites, showing high performance in repeatability.	https://ard.bmj.com/content/annrheumdis/79/Suppl_1/1830.1.full.pdf	2020
13	Non-comparative cohort study using REMS to demonstrate relationship between BMI and osteoporosis	Khu A, Sumardi M (2020) REMS Scan-Based Report on Relation Between Body Mass Index and Osteoporosis in Urban Population of Medan at Royal Prima Hospital. Majalah Kedokteran Bandung 52(1):22- 7	N-=300. Subjects were divided into normal, osteopenia, and osteoporosis based on the densitometry parameters. The median BMIs for Spine osteoporosis and Neck of Femur osteoporosis groups were 23.24 and 22.51, respectively. Meanwhile, the central tendency of the bone mass density (gr/cm2) of the spine and neck of femur osteoporosis were 0.70 and 0.53, respectively. There was a significant correlation between BMI and the incidence of the neck of femur (R coefficient =-0.690) and spine (R=-0.390) osteoporosis. Hence, lower BMI increases the potential of the neck of femur and spine osteoporosis.	https://www.echolight.it/wp-content/uploads/2020/07/Khu2020_indonesia.pdf	2020

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
14	Prospective cohort. Compares BMD measurements in pre- and post-menopausal women.	Kirilova E, Kirilov N, Popov I et al. (2019) Bone mineral density of lumbar spine and femoral neck assessed by novel echographic approach-Radiofrequency Echographic Multi Spectrometry (REMS). Clinical Cases in Mineral and Bone Metabolism 16(1)P14-17.	N=165. The mean REMS-based BMD measurements of postmenopausal group of L1-L4 and total lumbar spine were significantly lower than those of the premenopausal group (p=0.000). Femoral neck REMS based BMD (p=0.011), trochanteric REMS-based BMD (p=0.007) and total hip REMS-based BMD (p=0.009) also differed significantly between the premenopausal and postmenopausal group.	https://www.echolight.it/wp-content/uploads/2020/05/2019_CCMBM_Kirilova-et-al-REMS-in-Pre-e-Post-Menopausal-Women.pdf	2019
15	Prospective cohort study. Using REMS to categorise fracture risk for use in a Fracture Risk Assessment Tool (FRAX).	Kirilova E, Kirilov N, Popov I et al. (2019) Assessment of Fracture Risk through Radiofrequency Echographic Multi Spectrometry (REMS) based Bone Mineral Density. Orthopaedics and Rheumatology 15(1):22-27	N=189. Women were divided in 2 fracture risk groups: 1st – with FRAX score for major osteoporotic fracture below 20% and for hip fracture below 3%, and 2nd – with FRAX score for major osteoporotic fracture ≥ 20% and for hip fractures ≥3%.	https://www.echolightmedical.com/wp-content/uploads/2020/11/Kirilova2019_fratture.pdf	2019

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
16	Diagnostic accuracy of REMS for osteoporotic vs. non osteoporotic patients reported. Non-comparative report from a Prospective cohort from a comparison of REMS and DXA scans.	Ovejero Crespo D, Nogues X, Diez-Perez A (2019) The nonionizing radiofrequency echographic multi spectrometry (REMS) applied on a Spanish cohort for the osteoporosis diagnosis on lumbar spine and femoral neck. WCO-IOF-ESCEO Abstract P795	High REMS sensitivity of 92.7% and 93.0% and specificity of 93.5% and 95.0% for spinal and femoral site, respectively, for the discrimination between individuals with and without osteoporosis. The diagnostic accuracy of the REMS technique was also confirmed by the SEE value equal to 0.040 and 0.039 g/cm2 and the Cohen Kappa in the range 0.77-0.76 for spine and femur.	http://2019.wco-iof-esceo.org/sites/wco19/pdf/WCO19-AbstractBook.pdf	2019 Likely to be an abstract publication of a subpopulation of patients from Cortet 2021 multicentre study.

18. **Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only).** ***Please do not attach full text articles, this is just intended to be a summary.***

We are not currently aware of any yet to be published trials.

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

19. **List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

    Osteoporosis Australia / now renamed Healthy Bones Australia (Bone Health – Bone Health Website (healthybonesaustralia.org.au).

    Statement of clinical relevance:

    Healthy Bones Australia (HBA), formerly Osteoporosis Australia, is a national non-for-profit organisation and the leading consumer body to reduce broken bones and improve bone health across Australia. Healthy Bones Australia was established in 2001 in response to the growing number of Australians with poor bone health and the lack of health focus on preventing osteoporosis. Healthy Bones Australia is focused on increasing community and health professional awareness and advocating to government to reduce the impact of the osteoporosis nationally.

20. **List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):**

    The Australian Society of Medical Imaging and Radiation Therapy (ASMIRT)

    Endocrine Society of Australia (ESA)

21. **List the consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):**

    None identified

22. **List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:**

    Manufacturers of DXA Scans, e.g. MEDILINK, Norland, GE-Lunar, and Hologic

23. **Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):**

    REDACTED

PART 6 – POPULATION (AND PRIOR TESTS), INTERVENTION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

24. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality:

Information cited below is from the AIHW Osteoporosis Web Report (AIHW 2020): https://www.aihw.gov.au/getmedia/d89eda49-8e92-4045-996e-f38807142b2e/Osteoporosis.pdf.aspx?inline=true

Osteoporosis is a condition where bones become thin, weak and fragile, such that even a minor bump or accident can cause a broken bone (minimal trauma fracture). Osteopenia is a condition when bone mineral density is lower than normal but not low enough to be classified as osteoporosis. Such events might include falling out of a bed or chair, or tripping and falling while walking. Fractures due to osteoporosis can result in chronic pain, disability, loss of independence and premature death.

Generally, osteoporosis is under-diagnosed. Because osteoporosis has no overt symptoms, it is often not diagnosed until a fracture occurs. It is therefore difficult to determine the true prevalence of the condition (that is, the number of people with the condition). Information about 'diagnosed cases' is likely to underestimate the actual prevalence of the condition. An estimated 924,000 Australians have osteoporosis, based on self-reported data from the Australian Bureau of Statistics (ABS) 2017–18. National Health Survey (NHS) and 20% of people aged 75 years and over have osteoporosis (ABS 2018). This definition of osteoporosis includes people who had osteoporosis or osteopenia.

People aged 45 and over with osteoporosis had considerable adverse impacts from osteoporosis based on self-reported data from the ABS 2017–18 National Health Survey (NHS), including:

- lower self-assessed health status than people without the condition —. People with osteoporosis were 2.7 times as likely to describe their health as poor (15%) compared with those without the condition (5.4%).
- more than half of people with osteoporosis (57%) experienced 'moderate' to 'very severe' pain in the last 4 weeks. People with osteoporosis were 2.3 times as likely to experience severe or very severe bodily pain in the last 4 weeks (23%) compared with those without the condition (10%)
- being 2.9 times as likely to experience very high levels of psychological distress (12%) compared with those without the condition (4.1%).

In Australia in 2017–18 there were 93,321 hospitalisations for minimal trauma fractures in people aged 50 and over and 6,838 hospitalisations for osteoporosis for people aged 50 and over.

Diagnosis of osteoporosis requires an assessment of bone mineral density (BMD). The most commonly used technique is a specialised X-ray known as a 'Dual energy X-ray Absorptiometry (DXA) scan' to determine bone mineral density (BMD) in the hips and spine (IOF 2017). Scan results are expressed as T-scores which compare a person's BMD with the average of young healthy adults

Table 1: Diagnosing osteoporosis using bone density testing

	Normal	**Osteopenia**	**Osteoporosis**
T Score	1 to -1	-1 to -2.5	-2.5 or lower

Osteoporosis is largely a preventable disease. The goal of the prevention and treatment of osteoporosis is to maintain bone density and reduce a person's overall fracture risk (RACGP 2018). Primary prevention of osteoporosis involves supplementing diet to get sufficient calcium and vitamin D, and behaviour modification such as regular weight-bearing and resistance exercise, keeping alcohol intake low and not smoking, and fall reduction strategies (RACGP 2018). There is a diverse range of medicines available for osteoporosis management, so treatment selection is guided by a number of factors including sex, "menopausal status, medical history, whether it is for primary or secondary fracture prevention, patient preference and eligibility for government subsidy" (Bell et al. 2012).

25. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

It is proposed that patients currently eligible for DXA scanning (items 12306. 12312, 12315, 12320, 12321, 12322) would also be eligible for use of REMS, with the DXA items listed to help identify the analogous populations proposed. The patient would be investigated, managed and referred in the same way they currently are for DXA scanning prior to being considered eligible for REMS.

Use would be restricted to specific adult populations. Strict criteria on the frequency of use would be applied, i.e. usually requiring a minimum 24 month period between testing, except for the ≥70 years monitoring disease progression population where frequency would be ≥2 years or ≥5 years, depending on which range the tscore fell into). There are also some populations where the minimum frequency is 12 months, i.e. after proven low BMD diagnosis or for the monitoring of prolonged glucocorticoid therapy, excess glucocorticoid secretion, male hypogonadism or the specified female hypogonadism indication.

While generalised population screening is not proposed (being inconsistent with MBS listing, since the scheme does not usually cover screening programs), the following key populations are proposed as suitable, modelled on the eligible DXA scanning populations:

- **Diagnostic use (1):** People who have experienced minimal trauma fractures who require BMD status to be assessed in order to diagnose osteoporosis or another possible fracture cause.
- **Diagnostic use (2):** In populations with known, specified risk factors (listed in bullet points below).
- **Monitoring disease progression:** In populations previously diagnosed with low BMD via either DXA or REMS scanning (only allowed at appropriate, defined intervals).
- **Monitoring response to anti-osteoporosis medication:** People who have been diagnosed with osteoporosis via BMD measurements who have had a significant change in osteoporosis therapy (e.g. with use of bisphosphonates, denosumab, oestrogen replacement therapy, strontium renalate) more than 12 months prior.

Clinical trial data to support use in the key proposed populations would be provided, including in those aged over 70 years. Where possible subgroup analyses of the key studies would be used to support use across the proposed sub-populations.

It is proposed that Echolight/REMS technology would be used in place of DXA scanning to measure bone densitometry in:

1. Previously identified low BMD diagnosed based on fractures following minimal trauma or monitoring of low BMD proven by densitometry at least 12 months previously (analogous to item 12306)
2. Bone loss associated with prolonged glucocorticoid therapy, any condition associated excess glucocorticoid secretion, male hypogonadism, female hypogonadism lasting more than 6 months before the age of 45 (item 12312)
3. Bone loss associated with primary hyperparathyroidism, chronic liver disease, chronic renal disease, any proven malabsorptive disorder, rheumatoid arthritis, any condition associated with thyroxine excess (item 12315)
4. Patent aged 70 years of age or over who has not previously had densitometry or the t-score for the patient's BMD is less than 1.5, but not more than 2.5 (item 12320)
5. Established low BMD or confirming a presumptive diagnosis of BMD made on the basis of 1 or more fractures occurring after minimal trauma (item 12321)

6. Patient is over 70 years of age and the t-score is less than -1.5 but more than -2.5 (item 12322).

Patient management and referral would be consistent with existing patterns of osteoporosis risk assessment, diagnosis and management, as described under point 26.

As the REMS device can be portable, this may provide improved access to some high risk or 'hard to reach' populations who might present difficulties for a DXA scan. These include

1. regional and remote communities,
2. indigenous populations & communities,
3. Elderly & frail who have reduced mobility
4. Those with bone deformity / difficulty and cannot lie perfectly supine.

26. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

The current RACGP-recommended clinical management pathway for osteoporosis risk assessment, diagnosis and management is provided overleaf. Currently DXA scanning is recommended at 2 points in the management pathway, consistent with existing MBS reimbursement criteria (green boxes in diagram, plus recommended as an optional assessment in one other group):

1. Minimal trauma fracture at a site other than hip or vertebral fracture DXA scanning of spine and proximal femur is required.
2. No history of minimal trauma fracture a DXA scan of spine and proximal femur is recommended if aged ≥70 years or in younger patients, following risk factor profile assessment.
3. In patients with minimal trauma hip or vertebral fracture DXA scanning is recommended to establish baseline BMD, but not considered essential.

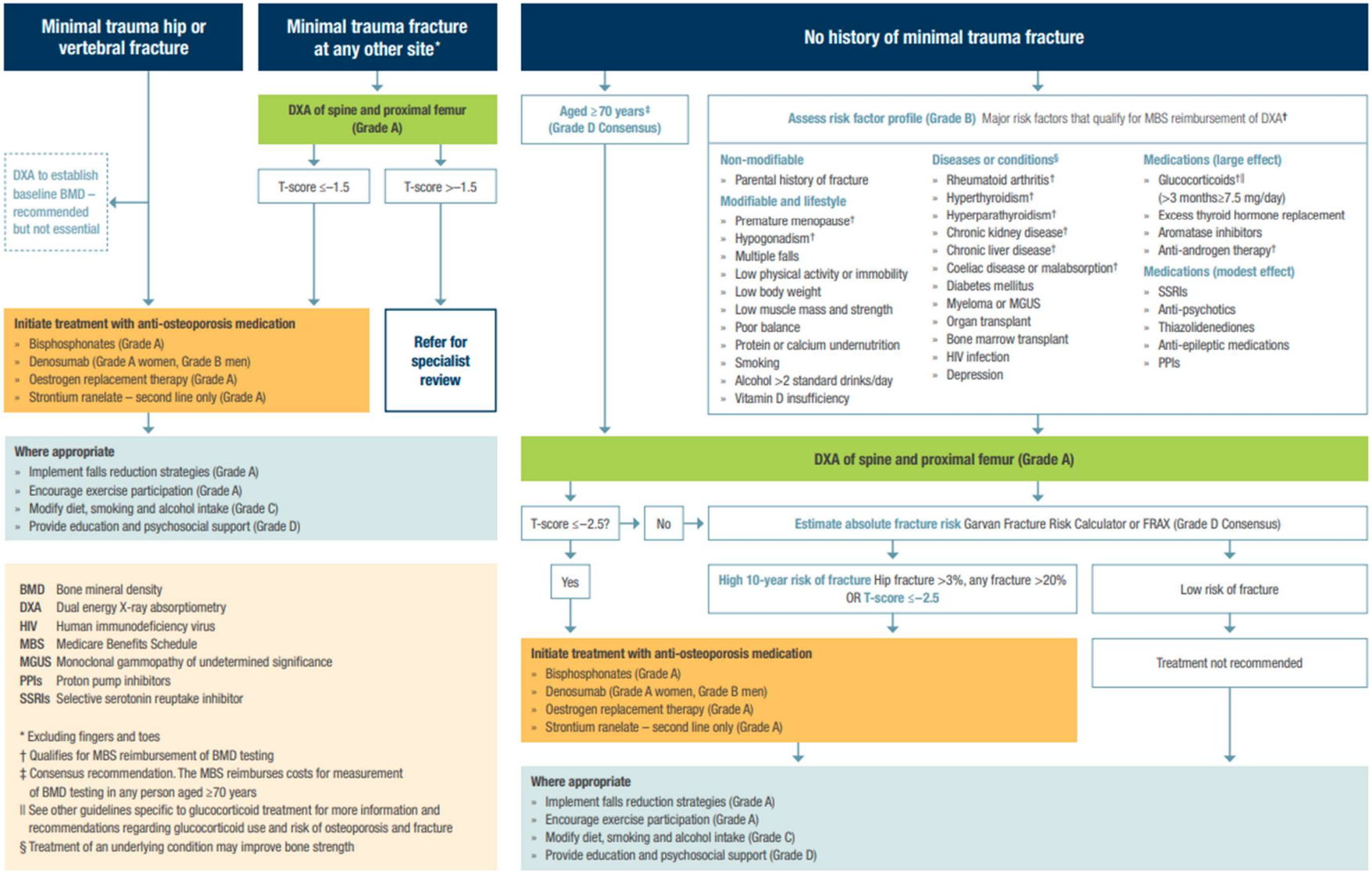
All steps in the current clinical management pathway prior to use of DXA scan would also apply prior to use of Echolight BMD/REMS testing (in place of DXA scanning), with Clinicians required to clinically assess either patients presenting with minimal trauma fracture or with risk factors for low BMD.

Source: https://www.racgp.org.au/download/Documents/Guidelines/Musculoskeletal/osteoporosis-algorithm.pdf

Osteoporosis risk assessment, diagnosis and management

Recommendations restricted to postmenopausal women and men aged >50 years

RACGP Royal Australian College *of* General Practitioners | osteoporosis australia



BMD Bone mineral density
DXA Dual energy X-ray absorptiometry
HIV Human immunodeficiency virus
MBS Medicare Benefits Schedule
MGUS Monoclonal gammopathy of undetermined significance
PPIs Proton pump inhibitors
SSRIs Selective serotonin reuptake inhibitor

* Excluding fingers and toes
† Qualifies for MBS reimbursement of BMD testing
‡ Consensus recommendation. The MBS reimburses costs for measurement of BMD testing in any person aged ≥70 years
‖ See other guidelines specific to glucocorticoid treatment for more information and recommendations regarding glucocorticoid use and risk of osteoporosis and fracture
§ Treatment of an underlying condition may improve bone strength

PART 6b – INFORMATION ABOUT THE INTERVENTION

27. Describe the key components and clinical steps involved in delivering the proposed medical service:

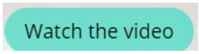
Overview

Echolight is a software-assisted, non-invasive echographic scan for evaluation of Bone Mineral Density at the lumbar vertebrae (L1-L4) and the femoral neck providing all the standard parameters for the diagnosis of osteoporosis, i.e. BMD, T-score, Z-score. The technology does not require radiological protection and is portable.

Echolight is a novel, non-invasive ultrasound device for bone characterisation and micro architecture assessment through scanning of central reference sites (lumbar vertebrae and proximal femur). Echolight technology is based on the new REMS (i.e. Radiofrequency Echographic Multi Spectrometry) method, an innovative ultrasound approach to the diagnosis of osteoporosis, which integrally exploits all the spectral features of the " radiofrequency (signals acquired during an echographic scan of the target anatomical site to determine the status of internal bone architecture.

An important feature of REMS method is the exploitation of RF signals acquired during an echographic scan of the target bone structure to determine the internal bone architecture through detailed comparisons with reference spectral models. Another important feature of the technology is its full automation, which reduces to a minimum the dependence on operator experience. In fact, the implemented algorithm automatically identifies and discards '' acquisitions, ensuring that diagnostic evaluations are performed only on ultrasound datasets reaching a specifically determined quality threshold.

A video of the use of Echolight, showing how the technology works and use in practice, is available on the manufacturers website.

Click on 

at https://www.echolightmedical.com/technology/ (accessed March 2021)

It is currently available in Australia at 2 sites, to provide key Physicians with access to the new technology.:

- One device is participating in a clinical study looking at the prevalence of low BMD in patients who have an genetic disease (i.e phenylketonuria & other Internal Errors of Metabolism).
- The other device is with a specialist who sits on the device advisory committee for Healthy Bones Australia (was Osteoporosis Australia).

The devices are provided free of charge to the sites and testing is free of charge to patients.

Technology used

Ultrasound scans are performed by Echolight echographic device equipped with a convex transducer operating at 3 5 MHz, allowing the simultaneous acquisition of conventional B mode images and corresponding unprocessed RF signals. The scan lasts about 1 min. REMS approach is based on the idea that RF signals, acquired during an echographic scan of a target bone district, can be used to determine the health status of the considered bone through advanced comparisons with previously derived reference spectral models of the possible pathological or normal conditions. This method is natively integrated with US imaging, combining

(a) the regions of interest (for diagnostic calculations within the investigated bone are automatically identified exploiting both morphologic details and RF spectral features, and,
(b) the simultaneous acquisition of several RF scan lines for each image frame provides a solid and reliable statistical basis for subsequent spectral processing.

Data analysis based on the correlation between frequency spectra of acquired RF signals and the appropriate reference models, is then able to calculate the respectively BMD, T score and Z scores.

Operation

To perform the diagnostic investigation, the operator should preliminarily visualize the first target interface (i.e. vertebra L 1 for lumbar acquisitions or femoral neck for hip scans) and set image depth and focal position to have the target interface in the central part of the image and in correspondence of the focus.

Afterwards, the software assisted ultrasound acquisition starts.

During the scan, the algorithm automatically detects the bone interfaces (red lines) and calculates the ROIs for data analysis (green areas). The automatic data processing is then started, including RF signal analysis and spectral comparison with reference models for calculation of diagnostic parameters and generation of the final medical report. REMS method provides two new numerical parameters:

1. OS which directly correlates with BMD measurements (in g/cm²) and consequently with DXA diagnostic evaluations (BMD T Score, Z Score), and
2. Fragility Score (FS; which is under development) which provides an independent estimate of bone fragility and fracture risk.

A detailed video shows how to use the Echolight device. Click on 

at https://www.echolightmedical.com/technology/

Output

The Echolight medical report contains all the common parameters for osteoporosis diagnosis through bone density assessment

- BMD (g/cm²),
- T Score, &
- Z Score.

In addition, FS evaluates the quality of internal bone micro architecture Finally, the 10 year risks of osteoporotic fractures (generic/ are calculated through the integrated FRAX ® software. Each patient can be examined and diagnosed in less than 2 min, ensuring the compliance of the protocol with time constraints of clinical routine.

(Source: Echolight Technology_Sheet_rev02_20180301_ENG-1)

28. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

No. Use of a different device for assessing BMD is proposed.

29. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

No, the use of a different device (i.e. REMS technology instead of DXA scanning) to measure BMD is the only proposed change.

30. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):

There are no limitations in the provision of the proposed service, with uptake expected post the proposed MBS-listing.

REMS technology has advantages over DXA scanning because it is

a. portable
b. does not use ionizing radiation,
c. easy to use – no specific qualification required – 1-2 days training of any healthcare professional would be sufficient to ensure competent operation.
d. Less expensive to operate the machine.
e. Does not require daily calibration as DXA does (REMs calibration is every 6 months)

However it will take time for the technology to become available to patients as it is adopted by Clinicians.

31. If applicable, identify any healthcare resources or other medical services that would need to be delivered <u>at the same time</u> as the proposed medical service:

None identified.

32. If applicable, advise which health professionals will primarily deliver the proposed service:

The operation of the device can be done by Ultrasonographers, REMs trained Nurses or General Practitioners (GPs) or Medical Specialists. It is proposed that the clinical interpretation would be done by either a specialist/consultant physician or trained Medical Practitioner

33. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:

A referral from a general practitioner or specialist/consultant physician would be required for the service.

34. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:

Referrals limited to GPs or Specialist or consultant physicians. Service may be provided by Specialist ultrasonography clinics or Specialist Clinics, using trained operators.

35. If applicable, advise what type of training or qualifications would be required to perform the proposed service, as well as any accreditation requirements to support service delivery:

Training with the Echolight/REMS device would be required prior to performing scans. The dedicated training and subsequent patient practice is conducted over 1 day (if familiar with osteoporosis and ultrasound) or over 2 days for all other healthcare professionals. This training will be provided by the Distributor.

36. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select <u>ALL</u> relevant settings):

- ☒ Inpatient private hospital (admitted patient)
- ☐ Inpatient public hospital (admitted patient)
- ☒ Private outpatient clinic
- ☐ Public outpatient clinic
- ☒ Emergency Department
- ☒ Private consulting rooms - GP
- ☒ Private consulting rooms – specialist
- ☐ Private consulting rooms – other health practitioner (nurse or allied health)
- ☐ Private day surgery clinic (admitted patient)
- ☐ Private day surgery clinic (non-admitted patient)
- ☐ Public day surgery clinic (admitted patient)
- ☐ Public day surgery clinic (non-admitted patient)
- ☒ Residential aged care facility
- ☐ Patient's home
- ☐ Laboratory
- ☐ Other – please specify below

Echolight can be provided in a range of healthcare settings with access to the device and trained operators and overview by specialist/consultant physician or trained Medical Practitioner providing interpretation/reporting.

(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:

Echolight scans provided in any healthcare setting that has the device available, trained operators and with oversight by a specialist/consultant physician or trained Medical Practitioner to provide interpretation/reporting.

37. Is the proposed medical service intended to be entirely rendered in Australia?

- ☒ Yes
- ☐ No – please specify below

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

38. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered at the same time as the comparator service):

Dual energy Xray absorptiometry (DXA)

39. Does the medical service (that has been nominated as the comparator) have an existing MBS item number(s)?

☒ Yes (please list all relevant MBS item numbers below)
☐ No

12306, 12312, 12315, 12320, 12321, 12322

40. Define and summarise the current clinical management pathway/s that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards, including health care resources):

Osteoporosis risk assessment, diagnosis and management should follow the RACGP Guidelines provided in point 26 (Accessed Jan 2021) available at:
https://www.racgp.org.au/download/Documents/Guidelines/Musculoskeletal/osteoporosis-algorithm.pdf

Patient management following use of an Echolight/REMS scan is expected to be the same as that following a DXA scan, as the same outputs used to determine treatment pathways are provided to Clinicians (i.e. T score). Following receipt of the T score, Clinicians may either monitor a patient, refer for specialist review or initiate treatment, depending on the clinical presentation (i.e. with or without minimal trauma fracture) and the T score obtained.

41. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?

☐ In addition to (i.e. it is an add-on service)
☒ Instead of (i.e. it is a replacement or alternative)

Echolight scans would be used as an alternative diagnostic methodology for some patients.

(b) If instead of (i.e. alternative service), please outline the extent to which the current service/comparator is expected to be substituted:

As this is very new technology and DXA has been considered the Gold Standards for decades, it is anticipated that switching / diagnosis vis Echolight / REMS technology will be slow and initially driven by Specialists. Estimates of switch from DXA to REMS technology is considered to be **REDACTED**.

It is not proposed that the results from REMS will have to always be confirmed with a DXA scan, however there may be some small amount of use of REMS in addition to DXA scans initially by some Clinicians as they become familiar with the technology.

The rate of discordant results between REMS and DXA would be expected to be low, with data to be presented from the comparative trials to demonstrate this. In the expected low number of cases where this occurred the DXA scanning result could be followed (since it is the current 'Gold standard'), rather than either test being repeated.

42. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service, including variation in health care resources (Refer to Question 39 as baseline):

There is no expected change to clinical management pathways post service delivery as a result of the introduction of Echolight/REMS.

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

43. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):

Use of Echolight/REMS scans instead of DXA provides a similar level of effectiveness (i.e. diagnostic accuracy). There is a similar level of safety during the procedure, with a potential for reduction in longer-term, cumulative harms due to the avoidance of ionising radiation as part of the process.

44. Please advise if the overall clinical claim is for:

☐ Superiority
☒ Non-inferiority

Note that while use of Echolight reduces the need for ionising radiation to be used (providing a potential long-term safety benefit), only equivalent efficacy and safety (i.e. assessed during the procedure) is claimed.

45. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

Safety Outcomes:

Safety outcomes not reported in the comparative trials.

Clinical Effectiveness Outcomes:

Key clinical effectiveness outcomes compare outcomes for the same patients at the same anatomical sites.

Correlation/agreement between REMS and BMD (g/cm^2) and/or T-scores at lumbar spine and femoral neck sites:

- Correlation between REMS and DXA BMD values determined by calculating the slope of the regression line, Pearson's correlation coefficient (r), the coefficient of determination (r^2) and the standard error of the estimate (SEE).

- some studies also reported these values for patient sub-populations with previous fracture history and those without previous fracture history (e.g. Adami et al. 2020).

Diagnostic accuracy of REMS vs. DXA based on categorisation of patients at lumbar spine and femoral neck sites - comparison of patients with and without osteoporosis based on T-score

(Categorisation as % patients with osteoporosis (T-score ≤ -2.5) or osteopenia (-2.5 < T-score <-1.0) or 'healthy patient' (T-score ≥ -1.0))

- Sensitivity (%)

- Specificity (%)

- Positive/negative predictive value (PPV, NPV) (%)

T-score based analysis for REMS vs. DXA:

- T score value distributions for each treatment with statistical treatment difference (p value)

Sensitivity in discriminating patients with and without previous osteoporotic fractures (%)

Specificity in discriminating patients with and without previous osteoporotic fractures (%)

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

46. Estimate the prevalence and/or incidence of the proposed population:

An estimated 924,000 Australians have osteoporosis, based on self-reported data from the Australian Bureau of Statistics (ABS) 2017–18 National Health Survey (NHS) and 20% of people aged 75 years and over have osteoporosis, with this definition of osteoporosis including people who had osteoporosis or osteopenia (AIHW 2020).

According to an audit of Australian general practice only 29% of patients with risk factors for osteoporosis had been screened for osteoporosis (Parker 2013). Additionally, 48% of patients with a previous scan for low BMD had not had recommended follow-up scans (Parker 2013).

Thus while the prevalence of osteoporosis in Australia is high in older age groups, only a proportion are currently accessing single or repeated DXA scans.

47. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:

The proposed MBS item descriptions limit use by a patient to once per 12 or 24 months or 5 years (Table 2), with the same criteria proposed for Echolight scans. Hence no patient would be expected to have more than 1 scan per year, with scans allowed only every 2 or 5 years for some patients.

This is because bone density loss is considered a relatively slow process and repeat testing within 24 months is unlikely to assist in clinical decision making. For specific medical conditions or particular treatments that may cause more rapid bone loss, a Medicare rebate is available for repeat testing at 12 monthly intervals (Source: https://www1.health.gov.au/internet/main/publishing.nsf/Content/diagnosticimaging-bd.htm)

Table 2: Services allowed per year for existing DXA scan MBS items

	MBS item					
	12306	**12312**	**12315**	**12320**	**12321**	**12322**
One service allowed per patient in:	24 months	12 months	24 months	5 years	12 months	2 years

48. How many years would the proposed medical service(s) be required for the patient?

Echolight scans would be performed according to clinical need at the maximum frequency described in Table 2. Most patients once diagnosed would be requested to undergo repeat scans for the remainder of their life, however this may only occur in less than 50% of patients (as described under point 46.).

49. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:

Information on the number of MBS services for DXA scans over the last 5 years is provided in

Table 3.

Based on the MBS services for DXA scans in the 2019/20 financial year, the projected number of patients likely to undergo Echolight scanning is estimated in Table 4. Since patients can only have a scan a maximum of once per year, or for some proposed MBS items only every 2-5 years, the proposed number of patients is likely to be the same as the proposed number of services.

Table 3: MBS Services for DXA scans

Year	Services by MBS item						Total
	12306	12312	12315	12320	12321	12322	
2015/2016	87,285	65,294	34,341	0	17,722	0	204,642
2016/2017	89,504	66,109	36,021	0	17,696	0	209,330
2017/2018	117,800	81,320	44,567	94,543	25,099	28,496	391,825
2018/2019	141,270	93,534	50,957	152,676	31,396	52,013	521,846
2019/2020	141,351	89,593	50,533	135,749	30,768	53,237	501,231
Total	577,210	395,850	216,419	382,968	122,681	133,746	1,828,874

Note, item 12323 was discontinued in November 2017 and replaced by items 12320 and 12320 that are time-restricted and based on BMD.

50. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:

The anticipated uptake of Echolight scans is provided in Table 4. Uptake will be constrained by the availability of the service, as Clinicians become aware of, investigate and then potentially start requesting REMS scans. Estimated uptake **REDACTED**.

Some patients who undergo DXA scans face 'out of pocket' costs. Depending on the level of subsidy provided following the proposed MBS listing, it is possible that some providers may also apply an 'out of pocket' cost to REMS services.

The greater portability of REMS compared with DXA means usage in rural and remote settings (e.g. remote indigenous communities) is likely. REMS may also be suitable for people who, because of disability or physical limitations, cannot undertake a DXA scan, but are suitable for REMS. While these factors may increase the population in whom it could be used, it is not expected to result in a substantial increase (this will be considered and estimated in the submission, based on expert advice or literature that can help quantify this).

There is a low likelihood of leakage to populations not targeted by the services, with patients currently having to pay privately for DXA scans that do not meet the existing criteria. This is likely to also occur in the future with Echolight scans being also used privately for non-MBS indications.

Echolight is manufactured in Italy. The timelines for obtaining the device are relatively short at 1-2 months, meaning that if funded, the REMS technology device could be ordered, arrive in Australia and operators could be trained in a timely manner.

Table 4: Anticipated uptake for proposed items consistent with the criteria for the DXA items

Year	Proposed services (analogous to existing MBS items)					
	12306	12312	12315	12320	12321	12322
1	**REDACTED**	**REDACTED**	**REDACTED**	**REDACTED**	**REDACTED**	**REDACTED**
2	**REDACTED**	**REDACTED**	**REDACTED**	**REDACTED**	**REDACTED**	**REDACTED**
3	**REDACTED**	**REDACTED**	**REDACTED**	**REDACTED**	**REDACTED**	**REDACTED**

PART 8 – COST INFORMATION

51. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:

The cost of providing the service is likely to be similar to DXA scans and a similar fee is proposed. Both procedures involve:

- Device purchase
- Staff training to competency
- patient preparation and consumables
- Staff salary time to perform the scan and
- interpretation recording by a Specialist/Consultant Physician or trained Medical Practitioner.

There may be some small cost savings versus DXA in that the salary of a nurse is probably less than an ultrasonographer.

Note that the likely cost breakdown is preliminary and will be further investigated with Australian Clinicians when preparing the listing submission.

52. Specify how long the proposed medical service typically takes to perform:

Whilst the actual scan / medical service typically takes around 2 minutes to perform, there is significant patient e preparation time required. This includes:

- Creating a patient file on the software
- Key risk factor questions
- The patient preparing for the scan and removing some clothing
- Positioning on the examination table (not always easy for elderly or those with mobility issues)
- Adjusting the REMS settings are accordingly
- Positioning and re-positioning the probe in the correct position for each scan (1-3 minutes depending on body size/shape/BMI etc.).
- Conducting the scan (1-2 minutes per site)
    - Importantly, the specialists we have spoken to have suggested that if possible – all three reference sites be scanned and that an average of the final patient's T-score be determined as the average across multiple sites.
- Ensuring the scan is valid and repeating the scan if found to be in-sufficient (this is determined immediately so the operator can repeat the scan without having to ask the patient to return)

53. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

Category 2: Diagnostic Procedures and Investigations – DN.1.18 Bone densitometry

Proposed item descriptor: See

Table 5

Fee: See

Table 5

The proposed MBS item descriptors and fees are provided in

Table 5. The proposed wording and fees are analogous to the DXA scanning items, with added/substituted wording in grey highlight and deleted wording crossed out.

Table 5: Proposed MBS item descriptors and fees

Category 2: Diagnostic Procedures and Investigations – DN.1.18 Bone Densitometry		
Analogous to MBS DXA item	**Proposed item descriptor**	**Proposed Fee***
12306	Bone densitometry, using Radiofrequency Echographic Multi Spectrometry dual energy Xray absorptiometry, involving the measurement of 2 or more sites (including interpretation and reporting), for: (a) confirmation of a presumptive diagnosis of low bone mineral density made on the basis of one or more fractures occurring after minimal trauma; or (b) monitoring of low bone mineral density proven by bone densitometry at least 12 months previously; other than a service associated with a service to which item 12312, 12315 or 12321 tbc applies For any particular patient, once only in a 24 month period	$105.60
12312	Bone densitometry, using Echographic Multi Spectrometry dual energy Xray absorptiometry, involving the measurement of 2 or more sites (including interpretation and reporting) for diagnosis and monitoring of bone loss associated with one or more of the following: (a) prolonged glucocorticoid therapy; (b) any condition associated with excess glucocorticoid secretion; (c) male hypogonadism; (d) female hypogonadism lasting more than 6 months before the age of 45; other than a service associated with a service to which item 12306, 12315 or 12321 tbc applies For any particular patient, once only in a 12 month period	$105.60
12315	Bone densitometry, using Echographic Multi Spectrometry dual energy Xray absorptiometry, involving the measurement of 2 or more sites (including interpretation and reporting) for diagnosis and monitoring of bone loss associated with one or more of the following conditions: (a) primary hyperparathyroidism; (b) chronic liver disease; (c) chronic renal disease; (d) any proven malabsorptive disorder; (e) rheumatoid arthritis; (f) any condition associated with thyroxine excess;	$105.60

Category 2: Diagnostic Procedures and Investigations – DN.1.18 Bone Densitometry		
Analogous to MBS DXA item	**Proposed item descriptor**	**Proposed Fee***
	other than a service associated with a service to which item 12306, 12312 or 12321 tbc applies For any particular patient, once only in a 24-month period	
12320	Bone densitometry, using Echographic Multi Spectrometry dual energy Xray absorptiometry or quantitative computed tomography, involving the measurement of 2 or more sites (including interpretation and reporting) for measurement of bone mineral density, if: (a) the patient is 70 years of age or over, and (b) either: (i) the patient has not previously had bone densitometry; or (ii) the t-score for the patient's bone mineral density is -1.5 or more; other than a service associated with a service to which item 12306, 12312, 12315, 12321 or 12322 tbc applies For any particular patient, once only in a 5 year period	$105.60
12321	Bone densitometry, using Echographic Multi Spectrometry dual energy Xray absorptiometry, involving the measurement of 2 or more sites at least 12 months after a significant change in therapy (including interpretation and reporting), for: (a) established low bone mineral density; or (b) confirming a presumptive diagnosis of low bone mineral density made on the basis of one or more fractures occurring after minimal trauma; other than a service associated with a service to which item 12306, 12312 or 12315 tbc applies For any particular patient, once only in a 12 month period	$105.60
12322	Bone densitometry, using Echographic Multi Spectrometry dual energy Xray absorptiometry or quantitative computed tomography, involving the measurement of 2 or more sites (including interpretation and reporting) for measurement of bone mineral density, if: (a) the patient is 70 years of age or over; and (b) the tscore for the patient's bone mineral density is less than 1.5 but more than 2.5; other than a service associated with a service to which item 12306, 12312, 12315, 12320 or 12321 tbc applies For any particular patient, once only in a 2 year period	$105.60

tbc, to be confirmed. * Based on March 2021 DXA scan fees.

References

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