MSAC application 1797

Vibration-Controlled Transient Elastography (VCTE™) for identifying advanced fibrosis in patients with metabolic dysfunction-associated fatty liver disease

Application for MBS eligible service or health technology

HPP Application number:

HPP200249

Application title:

Vibration-Controlled Transient Elastography (VCTE™) for identifying advanced fibrosis in patients with metabolic dysfunction-associated fatty liver disease

Submitting organisation:

HEALTH TECHNOLOGY ANALYSTS PTY LIMITED

Submitting organisation ABN:

13099239442

Application description

Succinct description of the medical condition/s:

MAFLD is a prevalent condition characterised by excessive fat accumulation in the liver due to metabolic dysregulation. It requires ≥5% hepatic steatosis along with at least one of the following: overweight/obesity, T2D, or metabolic dysfunction (defined by specific clinical and biochemical criteria) (Vaz, Clayton-Chubb et al. 2023). As fat continues to accumulate, MAFLD can progress from simple steatosis (fatty liver) to steatohepatitis, characterised by inflammation and liver cell damage. Persistent inflammation and liver cell damage can lead to the activation of hepatic stellate cells, which produce excess extracellular matrix proteins, resulting in fibrosis (Vancells Lujan, Viñas Esmel et al. 2021). Liver fibrosis is staged by its severity on a scale from zero (no fibrosis) to one (mild fibrosis), two (significant fibrosis), three (advanced fibrosis, AF) and four (cirrhosis) (Bedossa 2014).

Succinct description of the service or health technology:

The proposed investigative technology under evaluation in this document is Vibration Controlled Transient Elastography (VCTE™), a non-invasive diagnostic tool that assesses the extent of liver fibrosis. VCTE™ works by generating a mechanical pulse that creates a shear wave through the liver tissue. This measurement is converted into a numerical value expressed in kilopascals (kPa), known as the Liver Stiffness Measurement (LSM).

Patients are required to fast for at least 2 hours before taking the test. Once fasting is

complete, they should be placed in a supine position with their right arm positioned behind their head. The test requires a minimum of ten valid readings per patient, with at least a 60% success rate and an interquartile range of ≤30% of the median value being taken (Kemp 2013).

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?

Consultant

Are you applying on behalf of an organisation, or as an individual?

Organisation

Applicant organisation name:

Medical Technologies Australia PTY LTD

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prescribed List?

No

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?

New

Relevant MBS items

Please select any relevant MBS items.

MBS item number	Selected reason type

What is the type of service or health technology?

Investigative

Please select the type of investigative health technology: *(if investigative)*

Ultrasounds

PICO sets

PICO set 1 - [Vibration-Controlled Transient Elastography (VCTE™) for identifying advanced fibrosis in patients with metabolic dysfunction-associated fatty liver disease in primary care](#)

State the purpose(s) of the health technology for this PICO set and provide a rationale:

Purpose category:

Diagnosis / sub-classification

Purpose description:

To establish a diagnosis or disease (sub)classification in symptomatic or affected patients

Population
Describe the population in which the proposed health technology is intended to be used:

The population is patients with MAFLD, to test for advanced fibrosis. It is recommended that patients undergo an initial first line test with FIB 4 in primary care and those who have an indeterminate result between 1.3 and 2.7 should undergo VCTE™ testing.

Select the most applicable Medical condition terminology (SNOMED CT):

Non-alcoholic fatty liver disease

Intervention
Name of the proposed health technology:

VCTE™

Comparator
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). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

Referral for a liver ultrasound to identify stage of liver disease.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

The health and resource outcomes of interest in this application include:
• Test accuracy compared to liver biopsy (reference standard)
• Test accuracy compared to ultrasound (clinical utility standard)
• Prognostic accuracy
• Evaluation of patient management pathways in primary care
• Reduced referrals to secondary care

Proposed MBS items

Proposed item:

AAAAA

Proposed category:

PROFESSIONAL ATTENDANCES

Proposed group:

GENERAL PRACTITIONER ATTENDANCES TO WHICH NO OTHER ITEM APPLIES

Proposed item descriptor:

Vibration Controlled Transient Elastography at 50 Hz performed by a suitably trained health professional in primary care for the assessment of liver fibrosis in patients with metabolic dysfunction-associated fatty liver disease in addition to:
a. collection of relevant information, including taking a patient history; and
b. initiating interventions and referrals as indicated; and
c. implementing a management plan; and
d. providing the patient with preventative health care advice and information.
Used on the liver – 1 service only every 3 year - including interpretation and report

Proposed MBS fee:

$101.70

Indicate the overall cost per patient of providing the proposed health technology:

$101.70

Please specify any anticipated out of pocket expenses:

$0.00

Provide any further details and explain:

The proposed fee includes:
- Conducting VTCE™ scan
- Collect relevant information
- Initiating interventions and referrals as indicated
- implementing a management plan
- Providing the patient with preventative health care advice and information
- Item descriptor comparable to preventative MBS item 699 for a heart health assessment
- Reference fee taken from MBS item 82210 and 23

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

State-based funding in public hospitals and mobile tests performed in rural and regional areas are funded through local health services.

Self-funded by patients.

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

Superior

Please state what the overall claim is, and provide a rationale:

VCTE™ is superior to ultrasound for the detection and risk stratification of intermediate (F2) to AF (F3-F4).

VCTE™ provides quantitative measures of liver stiffness (measured in kPa), which correlates strongly with the degree of liver fibrosis and is highly accurate in identifying advanced fibrosis (F3) and cirrhosis (F4) with validated cut-off values. Ultrasound is qualitative, assessing liver texture, echogenicity, and vascular changes and therefore has poor sensitivity in determining presence of advanced fibrosis.

Additionally, VCTE™ provides valuable prognostic information about the risk of future LREs, including HCC and mortality. Therefore, helping GPs in timely identification of those at-risk of disease progression and plan appropriate patient management.

Estimated utilisation

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

There is a paucity of data regarding the true prevalence of fatty liver disease in Australia and no data on the prevalence of MAFLD (Mahady and Adams 2018). However, the prevalence of NAFLD can be estimated from one article modelling liver disease burden by Adams et al. (Adams, Roberts et al. 2020). The prevalence of NAFLD in Australia is projected to increase significantly between 2019 and 2030: NAFLD (F2) stage cases

- In 2019: Estimated 228,000 cases (range: 142,000 to 345,000)
- Projected for 2030: 347,000 cases (range: 218,000 to 524,000)
- Expected increase: 50%

AF (F3) stage cases

- In 2019: Estimated 133,000 cases (range: 79,100 to 193,000)
- Projected for 2030: 223,000 cases (range: 134,000 to 322,000)
- Expected increase: 70%

These projections indicate a substantial growth in the number of Australians affected by more advanced stages of NAFLD over the next decade, with F3 cases showing a particularly sharp rise.

The high prevalence of MAFLD in rural areas may have significant implications for clinical outcomes. Previous data from Melbourne showed NAFLD as the primary risk factor for 14% of HCC cases.

A recent study comparing diabetes prevalence in rural communities between 2001-2003 and 2016-2018 revealed an increase in age-standardised diagnosed diabetes from 5.0% to 7.7% (Simmons, Glenister et al. 2020). These findings underscore the importance of addressing NAFLD/MAFLD and associated risk factors in both rural and urban Australian populations (Kemp, Clayton-Chubb et al. 2022).

It's important to note that while approximately 30% of Australians live in regional or remote areas, these findings may not be directly applicable to all rural or metropolitan communities (Kemp, Clayton-Chubb et al. 2022).

Furthermore, up to 60% of NAFLD patients require additional tests for assessment of significant fibrosis (Vaz, Kemp et al. 2023).

Hence, uptake rate accounts for clinician uptake (variable), device availability

(variable), need for additional testing for patients with MAFLD, and proportion of Australian living in rural and remote areas (30%).

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):

20

Year 2 estimated uptake (%):

30

Year 3 estimated uptake (%):

40

Year 4 estimated uptake (%):

50

Estimate the number of patients who will utilise the proposed technology for the first full year:

29000

Optionally, provide details:

Current estimations would be around 45,000 patients given modelled prevalence rate, need for additional testing given indeterminate results and estimated utilisation given limited device availability. To be estimated on projected F2-F3 stage cases and sensitivity studies of an indeterminate FIB 4 result, and number of patients who live in regions that do not have specialist access to hepatologists.

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

10

Optionally, provide details:

VCTE™ is recommended to be used once every 3 years on patients with MAFLD based on upcoming Consensus statement to be published by the Gastroenterological Society of Australia (GESA).

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

0.3

Optionally, provide details:

3 VCTE™ tests per 10 years (0.3 tests per year).

PICO set 2 - [Vibration-Controlled Transient Elastography (VCTE™) for identifying advanced fibrosis in patients with metabolic dysfunction-associated fatty liver disease in specialist care](#)

State the purpose(s) of the health technology for this PICO set and provide a rationale:

Purpose category:

Diagnosis / sub-classification

Purpose description:

To establish a diagnosis or disease (sub)classification in symptomatic or affected patients

Population

Describe the population in which the proposed health technology is intended to be used:

The population is patients with MAFLD in specialist care, to test for advanced fibrosis. It is recommended that patients undergo an initial first line test with FIB 4 in primary care and those who have an indeterminate result between 1.3 and 2.7 should undergo VCTE™ testing in specialist care where available.

Select the most applicable Medical condition terminology (SNOMED CT):

Non-alcoholic fatty liver

Intervention

Name of the proposed health technology:

VCTE™

Comparator

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).

This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

Referral for a liver ultrasound to identify stage of liver disease and plan appropriate patient management

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

The health and resource outcomes of interest in this application include:
- Test accuracy compared to liver biopsy (reference standard)
- Test accuracy compared to ultrasound (clinical utility standard)
- Prognostic accuracy

Proposed MBS items

Proposed item:

AAAAA

Proposed category:

PROFESSIONAL ATTENDANCES

Proposed group:

HEALTH ASSESSMENTS

Proposed item descriptor:

Vibration Controlled Transient Elastography at 50 Hz performed by a suitably trained health professional in specialist care for the assessment of liver fibrosis in patients with metabolic dysfunction-associated fatty liver disease in addition to:

a. collection of relevant information, including taking a patient history; and
b. initiating interventions and referrals as indicated; and
c. implementing a management plan; and
d. providing the patient with preventative health care advice and information.

Used on the liver – 1 service only every 3 year - including interpretation and report

Proposed MBS fee:

$141.75

Indicate the overall cost per patient of providing the proposed health technology:

$141.75

Please specify any anticipated out of pocket expenses:

$0.00

Provide any further details and explain:

The proposed fee includes:
- Conducting VTCE™ scan
- Collect relevant information
- Initiating interventions and referrals as indicated
- implementing a management plan
- Providing the patient with preventative health care advice and information
- Is benchmarked against comparable preventative MBS item 699 for a heart health assessment
- Reference fee taken from MBS item 82210 and 104

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

State-based funding in public hospitals and mobile tests performed in rural and regional areas are funded through local health services.

Self-funded by patients.

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

Superior

Please state what the overall claim is, and provide a rationale:

VCTE™ is superior to ultrasound for the detection and risk stratification of intermediate (F2) to AF (F3-F4).

VCTE™ provides quantitative measures of liver stiffness (measured in kPa), which correlates strongly with the degree of liver fibrosis and is highly accurate in identifying advanced fibrosis (F3) and cirrhosis (F4) with validated cut-off values. Ultrasound is qualitative, assessing liver texture, echogenicity, and vascular changes and therefore has poor sensitivity in determining presence of advanced fibrosis.

Additionally, VCTE™ provides valuable prognostic information about the risk of future LREs, including HCC and mortality. Therefore, helping clinicians in timely identification of those at-risk of disease progression and plan appropriate patient management.

Estimated utilisation

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

There is a paucity of data regarding the true prevalence of fatty liver disease in Australia and no data on the prevalence of MAFLD (Mahady and Adams 2018). However, the prevalence of NAFLD can be estimated from one article modelling liver disease burden by Adams et al. (Adams, Roberts et al. 2020). The prevalence of NAFLD in Australia is projected to increase significantly between 2019 and 2030:

NAFLD (F2) stage cases
- In 2019: Estimated 228,000 cases (range: 142,000 to 345,000)
- Projected for 2030: 347,000 cases (range: 218,000 to 524,000)
- Expected increase: 50%

AF (F3) stage cases
- In 2019: Estimated 133,000 cases (range: 79,100 to 193,000)
- Projected for 2030: 223,000 cases (range: 134,000 to 322,000)
- Expected increase: 70%

These projections indicate a substantial growth in the number of Australians affected by more advanced stages of MAFLD over the next decade, with F3 cases showing a particularly sharp rise.

Furthermore, up to 60% of NAFLD patients require additional tests for assessment of significant fibrosis (Vaz, Kemp et al. 2023).
Hence, uptake rate in specialist accounts for clinician uptake (variable), need for additional testing for patients with MAFLD.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):

40

Year 2 estimated uptake (%):

50

Year 3 estimated uptake (%):

60

Year 4 estimated uptake (%):

70

Estimate the number of patients who will utilise the proposed technology for the first full year:

85000

Optionally, provide details:

Current estimations would be around 85,000 patients given modelled prevalence rate, need for additional testing given indeterminate results and device availability in speciality care. To be estimated on projected F2-F3 stage cases and sensitivity studies of an indeterminate FIB 4 result in specialist care.

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

10

Optionally, provide details:

To be defined given average disease progression and treatment. VCTE™ is recommended to be used once every 3 years on patients with MAFLD based on GESA MAFLD Consensus statement.

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

0.3

Optionally, provide details:

Consultation

List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.

Entities who provide the health technology/service

Gastroenterological Society of Australia

Royal Australian College of General Practitioners

Royal Australasian College of Physicians

Entities who request the health technology/service

Gastroenterological Society of Australia

Royal Australian College of General Practitioners

Royal Australasian College of Physicians

Entities who may be impacted by the health technology/service

Gastroenterological Society of Australia

Royal Australian College of General Practitioners

Royal Australasian College of Physicians

Patient and consumer advocacy organisations relevant to the proposed service/health technology

Liver Foundation

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?

Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

Yes

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

No

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
151894	Medical Technologies Aust Pty Ltd - Hepatic ultrasound elastography generator/analyser
206567	Medical Technologies Aust Pty Ltd - Hepatic ultrasound elastography applicator

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?

Yes