MSAC application 1825

Transcranial Doppler bubble test for patent foramen ovale

Application for MBS eligible service or health technology

HPP Application number:

HPP200340

Application title:

Transcranial Doppler bubble test for patent foramen ovale

Submitting organisation:

AUSTRALIAN AND NEW ZEALAND STROKE ORGANISATION LTD

Submitting organisation ABN:

69089885441

Application description

Succinct description of the medical condition/s:

PFO-associated stroke is a type of stroke attributed to a common congenital anomaly of the heart, referred to as patent foramen ovale or PFO. A PFO is a tunnel between the right and left atria of the heart. PFO occurs in 25% of the population. In a minority of these persons a blood clot can pass through the PFO, or form in the PFO tunnel itself, and then lead to stroke.

Succinct description of the service or health technology:

The transcranial Doppler (TCD) bubble test involves using a standard ultrasound device to monitor blood flow through brain arteries at rest, after injection of agitated saline into a vein in the arm, and after injection of agitated saline whilst the subject is doing a Valsalva manoeuvre. Agitated saline is prepared by mixing normal saline with a small quantity of air and the subject's own blood using a syringe plunger. The Valsalva manoeuvre is where the subject is asked to forcibly exhale but without releasing air and the purpose of this is to increase pressure in the chest. In a person with a PFO, the TCD machine detects tiny air bubbles in the brain arteries, referred to as embolic signals. They are detected as blips on the TCD display and are accompanied by audible chirps. A big PFO will result in a curtain response, where there are too many ES to count.

Application contact details

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

Applicant

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

Organisation

Applicant organisation name:

AUSTRALIAN AND NEW ZEALAND STROKE ORGANISATION 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

What is the type of service or health technology?

Investigative

Please select the type of investigative health technology:

Ultrasounds

PICO sets

Application PICO sets:

PICO set name
Patients with cryptogenic stroke

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

Purpose category:
Targeted testing

Purpose description:
To test currently unaffected or asymptomatic individual(s) identified as at increased risk for the condition. For example: cascade testing

Purpose category:
Value of knowing

Purpose description:
Tests may also provide additional non-health value to patients or to their family members and carers, and discussion of these outcomes could supplement an assessment of the clinical utility of the technology.

What additional purpose(s) could the health technology be used for, other than the purposes listed above for this PICO set?

Purpose category:
Outcome / response assessment

Purpose description:
To assess an outcome or response following an intervention or treatment

Rationale:
This applies only to people who have undergone percutaneous endovascular closure of a PFO. The test is used to determine if the procedure was successful.

Population

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

Patients with cryptogenic stroke

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

Patent foramen ovale

Intervention

Name of the proposed health technology:

Transcranial Doppler bubble test

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:

The alternative diagnostic pathway is TTE with bubble test. There can be a delay of a couple of months. Sometimes the TTE is not performed with a bubble test and it might need to be repeated. Often, a TOE must be performed as well, as TTE with bubble test Is less sensitive than a TCD bubble test. In the public hospital system, the wait time for a TTE, then outpatient review, then TOE, then another outpatient review, can result in a delay of up to a year before a patient with PFO-associated stroke receives targeted treatment. Not only is this stressful for patients, but some patients will also have an interim stroke, which can be extremely costly to society, especially as those with PFO-associated stroke are often of working age.

Outcomes

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

More widespread use of the TCD bubble test will enable more timely diagnosis and treatment of PFO-associated stroke. Furthermore, it will reduce the number of patients referred for TTE with bubble test (which is less sensitive for detection of PFO) and TOE (which is more costly, less available, and invasive).

Proposed MBS items

Proposed item: AAAAA

Category number:

2

Category description:

D1

Proposed item descriptor:

Bubble study for detection of patent foramen ovale in patient with previous ischaemic stroke. Must be performed by an accredited sonographer, in an accredited practice, using a registered TCD or TCCD device, with an attending medical practitioner or accredited health professional.

Proposed MBS fee:

$250.00

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

$250.00

Please specify any anticipated out of pocket expenses:

$0.00

Provide any further details and explain:

There may be a gap fee for non-hospitalised patients

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

Using item number 11614 which is inadequate

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:

Superior sensitivity. More accessible (where test available) than comparators.

Estimated utilisation

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

Approximately 11500 patients less than 65 years of age suffer stroke in Australia every year. Of these approximately 3800 have cryptogenic stroke. Of these approximately 1500 have PFO-associated stroke.

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

Year 1 estimated uptake (%):

10

Year 2 estimated uptake (%):

20

Year 3 estimated uptake (%):

30

Year 4 estimated uptake (%):

40

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

Up to 1500 patients

Optionally, provide details:

This will depend on how quickly the test can be rolled out by stroke units around Australia.

Will the technology be needed more than once per patient?

No, once only

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.

Entity who provides the health technology/service

AUSTRALIAN AND NEW ZEALAND STROKE ORGANISATION LTD

AUSTRALASIAN STROKE ACADEMY LTD

AUSTRALIAN AND NEW ZEALAND ASSOCIATION OF NEUROLOGISTS

Entity who requests the health technology/service

AUSTRALIAN AND NEW ZEALAND STROKE ORGANISATION LTD

AUSTRALASIAN STROKE ACADEMY LTD

AUSTRALIAN AND NEW ZEALAND ASSOCIATION OF NEUROLOGISTS

Entity who may be impacted by the health technology/service:

AUSTRALIAN AND NEW ZEALAND STROKE ORGANISATION LTD

AUSTRALASIAN STROKE ACADEMY LTD

AUSTRALIAN AND NEW ZEALAND ASSOCIATION OF NEUROLOGISTS

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

NATIONAL STROKE 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
119626	DWL-DopplerBox, Multi-DopT, Multi-DopX, Embo-Dop, EZ-Dop Systems - Ultrasound system, non-imaging, Doppler blood-flow measurement
292236	Noninvasive vascular ultrasound system, line-powered
387110	Ultrasound system, imaging, general-purpose
462120	Ultrasound system, imaging, general-purpose

Is the therapeutic good classified by the TGA as for Research Use Only (RUO)?

No

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

Yes