

MSAC application 1826

**N-Terminal-pro Brain Natriuretic
Peptide (NT-proBNP) testing to
support management of patients with
heart failure**

Application for MBS eligible service or health technology

HPP Application number:

HPP200346

Application title:

N-Terminal-pro Brain Natriuretic Peptide (NT-proBNP) testing as an aid for the management of patients with heart failure

Submitting organisation:

ROCHE DIAGNOSTICS AUSTRALIA PTY LIMITED

Submitting organisation ABN:

29003001205

Application description

Succinct description of the medical condition/s:

Heart failure is a complex clinical syndrome which means that the heart cannot pump enough blood to meet the body's physical needs or can only do so with abnormally high pressure in the heart. Heart failure that occurs or worsens suddenly is a medical emergency that can lead to death without medical intervention. It is diagnosed based on symptoms (breathlessness, cough or wheeze, and fatigue or significant restriction in physical activities), clinical signs (increased pressures in important veins, fluid retention or oedema, changes in breath sounds in the lungs), and objective measures such as physical changes in the heart or changes in blood tests such as NT-proBNP. Around 70,000 people have an initial or first admission to hospital for heart failure every year in Australia; more than half may also have one or more emergency re-admissions. Treatment with evidence-based or guideline-directed medication therapy is essential to reduce the risk of dying or returning to hospital.

Succinct description of the service or health technology:

NT-proBNP levels in the blood increase when the heart is stretched or is under higher levels of mechanical stress. Elevated NT-proBNP can be tested as part of diagnosing heart failure in hospital emergency departments. Testing for NT-proBNP levels can be used to guide decisions about increasing or titrating medication doses for individual patients, meaning that a higher proportion of patients are treated with optimised GDMT and have lower risk of death or of re-admission to hospital for heart failure.

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:

ROCHE DIAGNOSTICS AUSTRALIA PTY LIMITED

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
66586	Other
66829	Other
66830	Prerequisite item
66585	Other

What is the type of service or health technology?

Investigative

Please select the type of investigative health technology:

Clinical biochemistry

PICO sets

Application PICO sets:

PICO set name
N-Terminal-pro Brain Natriuretic Peptide (NT-proBNP) testing as an aid for the management of patients with heart failure

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

Purpose category:

Outcome / response assessment

Purpose description:

To assess an outcome or response following an intervention or treatment

Purpose category:

Predictive

Purpose description:

To provide predictive information to support selection of a specific therapy or intervention

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

Purpose category:

Diagnosis / sub-classification

Purpose description:

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

Rationale:

The use of NT-proBNP testing for diagnosis is already included in the Medicare Benefits Schedule. Relevant items are:

Item 66829 (Quantitation of BNP or NT-proBNP for the exclusion of a diagnosis of

heart failure in a patient presenting in a non-hospital setting to assist in decision-making regarding the clinical necessity of an echocardiogram, where heart failure is suspected based on signs and symptoms but diagnosis is uncertain)
Item 66830 (Quantitation of BNP or NT-proBNP for the diagnosis of heart failure in patients presenting with dyspnoea to a hospital Emergency Department)

Population

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

Key population characteristics are:

- Diagnosed with heart failure as part of a hospital admission, and/or admitted to hospital for treatment for heart failure.
- Intended to be treated or managed with at least three of the four classes of guideline directed medical therapy, including an angiotensin-converting enzyme inhibitor (ACEi), beta blocker, mineralocorticoid receptor antagonist (MRA), and / or sodium-glucose cotransporter 2 inhibitors (SGLT2i)
- An initial NT-pro BNP measurement either during or immediately prior to hospital admission of more than 2500 pg / mL
- Not currently treated with greater than 50% of maximum doses of GDMT (ACEi, MRA, beta blocker)

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

Heart failure

Intervention

Name of the proposed health technology:

NT-proBNP testing as an aid for the management of patients with HF

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:

Nomination of comparators for NT-proBNP testing for treatment optimisation was informed by the recommended modalities for pharmacological management of chronic HF outlined in the CSANZ Heart Failure Guidelines 2018. Based on the recommendations made in this clinical practice guidelines several comparators are nominated.

Blood Biochemistry - For each dose escalation of angiotensin-converting enzyme inhibitor (ACEi) and mineralocorticoid receptor antagonists (MRA), blood biochemistry is recommended to monitor renal function and potassium levels.

Observations (i.e. bradycardia, congestion, cough and angioedema) - For ACEi escalation, it is recommended to monitor for ACEi cough and angioedema. Monitoring for bradycardia is recommended when escalating beta blockers. Signs of congestion typically reflect symptoms of HF, therefore worsening congestion would suggest dose escalation of diuretic.

Vitals (i.e. blood pressure and heart rate) - Blood pressure, heart rate and clinical evaluation of volume status are important vitals for beta blocker escalation. Blood pressure is also essential when escalating ACEi and MRAs.

Outcomes

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

NT-proBNP testing for treatment optimisation should be used alongside existing tests, such as blood biochemistry and physicals (observations and vital signs), when considering dose escalation. While usual care primarily informs clinicians when not to escalate treatment, NT-proBNP levels provide additional guidance by indicating when it is appropriate to up-titrate or pause therapies. This is facilitated through a traffic light system, as shown in Figure 1, which gives clinicians greater confidence in

making timely and appropriate treatment decisions. Therefore NT-proBNP testing for treatment optimisation leads to:

- A change in patient management, providing clinicians with guidance on when to up-titrate or pause treatment—particularly beta blockers for cardiac remodelling and diuretics used for symptomatic relief - with full dose up-titration occurring within 6 weeks post-discharge;
- Reduced risk of 180-day HF readmission, due to the intensified regime of NT-proBNP testing for treatment optimisation; and therefore
- Reduced risk of 180-day all-cause death.
- Higher proportion of patients on optimal doses of GDMT.

Proposed MBS items

Proposed item: AAAAA

MBS item number (where used as a template for the proposed item):

NA

Category number:

PATHOLOGY SERVICES

Category description:

CHEMICAL

Proposed item descriptor:

Quantitation of NT-proBNP levels in patients with heart failure:

- (a) where a patient has an NT-proBNP level of greater 2,500 pg/ml; and
- (b) patients not currently on optimal treatment; and
- (c) to guide the optimisation of heart failure therapy.

Applicable to a maximum of 5 tests per patient in any 12 month period.

Proposed MBS fee:

\$58.50

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

\$248.75

Please specify any anticipated out of pocket expenses:

\$0.00

Provide any further details and explain:

The proposed MBS fee is \$58.50, therefore at 85% benefit the cost is \$49.75 per test. Based on up to five tests per patient, the maximum total cost per patient is \$248.75. However, the actual cost is expected to be lower, depending on the number of tests provided. Note that this overall cost estimate does not include cardiologist or GP consultation time, and therefore fees.

At this stage, cost estimates do not include additional primary care specialist attendance items. Impact on attendances may need to be considered as part of the economic modelling in the assessment report. Current guidelines in Australia (CSANZ, 2018) recommend multiple options for optimising post-discharge care, including through nurse-led or multidisciplinary titration clinics, primary care follow-up, or telehealth models. The 2018 recommendation suggests that there are existing models of care and clinical services that support titration; the introduction of NT-proBNP for rapid optimisation may therefore change the timing or scheduling of these services, but may not require net additional attendance items claimed as Medicare benefits. Sensitivity analysis will be conducted as part of the full assessment report to test the extent to which cost-effectiveness is reduced based on potential additional costs for attendance items.

In conjunction with the proposed item descriptor, a practice note is proposed to ensure multidisciplinary care is under specialist supervision, similar to that of PN.2.5 for scleroderma. See below for proposed practice note:

Where MBS item XXXX is requested by a medical practitioner (other than a specialist or consultant physician), the request should be made in consultation with a specialist or consultant physician who manages the treatment of the patient.

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

BNP and NT-proBNP testing are currently funded under the MBS for specific indications, including scleroderma, monitoring of pulmonary arterial hypertension,

and the diagnosis of HF in emergency departments and non-hospital settings. NT-proBNP testing is not MBS listed for treatment optimisation in heart failure patients. However, access and uptake are limited, with availability confined to a small number of public hospitals, such as Blacktown Hospital using local health district funding.

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:

NT-proBNP provides insights into biomechanical stress, and therefore persistent congestion in heart failure, guiding clinical decisions for optimising beta-blockers and diuretics as part of guideline-directed medical therapy (GDMT). Evidence will support this claim with improved GDMT uptake, reduced readmissions, and better survival outcomes.

Our claim is that the use of NT-proBNP testing to guide treatment optimisation will be superior to usual care consisting of biochemistry tests, vital signs, and clinical observations alone.

Estimated utilisation

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

Eligibility for the proposed health technology requires an index (or initial) hospital admission for heart failure. This means that overall prevalence of heart failure (including chronic and acute heart failure) or incidence of newly-diagnosed heart failure (which may include heart failure diagnosed without a hospital admission) may not be an effective estimate of the proposed population. An analysis of linked hospital and community-based data published by the Australian Institute of Health and Welfare (AIHW Cat No CVD 101) has been used to estimate annual hospitalisations for heart failure. The upper bound of this range, approximately 254 patients per 100,000 Australians, is used as the estimate of the proposed annual population for this application.

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 (%):

40

Year 4 estimated uptake (%):

80

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

7150

Optionally, provide details:

Uptake of the proposed health technology has been estimated based on clinical expert input. As noted above, uptake of the proposed technology is dependent on changes to local care pathways (i.e. to enable access to follow-up consultations for medication dose adjustment / utilisation of NT-proBNP results to inform treatment decisions). Although this may be a barrier to uptake of this technology initially, there is evidence in the Australian health system of willingness to change treatment pathways specifically for heart failure to improve patient outcomes (see, for example, Safer Care Victoria-led improvement project in heart failure).

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:

The Royal College of Pathologists of Australasia (RCPA)

Entity who requests the health technology/service:

Cardiac Society of Australia and New Zealand (CSANZ)

Royal Australian College of General Practitioners (RACGP)

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

Cardiac Society of Australia and New Zealand (CSANZ)

Royal Australian College of General Practitioners (RACGP)

Royal College of Pathologists of Australasia (RCPA)

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

Heart Foundation

Hearts 4 Hearts

Entity who produces similar products:

Abbott Diagnostics

BioMerieux

Ortho Clinical Diagnostics

Radiometer

Siemens Healthineers

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
200275	Clinical chemistry - Clinical chemistry-specific protein IVDs

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

Yes

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

No