

# **MSAC Application 1781**

**Risk assessment in prostate cancer using  
the Stockholm3 multiparametric blood test**

# Application for MBS eligible service or health technology

**ID:**

HPP200090

**Application title:**

Risk Assessment in Prostate Cancer using the Stockholm3 Multiparametric Blood Test

**Submitting organisation:**

LUCID HEALTH CONSULTING PTY LTD

**Submitting organisation ABN:**

11608882971

## Application description

**Succinct description of the medical condition/s:**

Prostate cancer.

**Succinct description of the service or health technology:**

The Stockholm3 is a multiparametric blood-based test that uses protein and genetic analysis combined with clinical data and an algorithm to estimate the risk of having clinically significant prostate cancer.

## 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

**Is the applicant organisation the organisation you are representing in the HPP today?**

No

**Applicant Organisation Details**

**Australian Business Number (ABN):**

**Applicant organisation name:**

A3P Biomedical

## 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

**Please select any relevant MBS items.**

**MBS item number**

**Selected reason type**

66654

Prerequisite item

66655

Prerequisite item

**What is the type of service or health technology?**

Investigative

**Please select the type of investigative health technology:**

Other

**Please provide details of 'Other' health technology type:**

Multiparametric blood test using protein analyses, genetic analyses, clinical data and an algorithm to stratify the risk of prostate cancer.

## **PICO Sets**

**Application PICO sets**

**PICO set number**

**PICO set name**

1

Multiparametric blood test combined with clinical data and an algorithm (Stockholm3) for the assessment of the risk of prostate cancer for men aged 45 to 74 years without a previous prostate cancer diagnosis with a PSA of 1.5ng/ml or above.

**Multiparametric blood test combined with clinical data and an algorithm (Stockholm3) for the assessment of the risk of prostate cancer for men aged 45 to 74 years without a previous prostate cancer diagnosis with a PSA of 1.5ng/ml or above.**

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

**Purpose category:**

Other

**Purpose description:**

## Supporting documentation

### Document type

#### File name(s)

Application PICO set documents

20231105 Stockholm3 MBS Application PICO set.Final.docx

Reference list

Reference List.docx

## Population

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

Stockholm3 is intended for males aged 45 to 74 years without a prior prostate cancer diagnosis with PSA levels of 1.5ng/ml and above.

### Search and select the most applicable Medical condition terminology (SNOMED CT):

Primary carcinoma of prostate

## Intervention

### Name of the proposed health technology:

Stockholm3

## 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:

Prostate specific antigen (PSA) alone.

In the absence of Stockholm3, men may receive a PSA test if they are aged 45 to 74 years depending on risk factors and anticipated life span. It is recommended that men with a family history of prostate cancer be offered the test from 45 years and all other men from 50 years. It is recommended that the PSA test be conducted every 2 years.

## Outcomes

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

Stockholm3 helps guide the management of patients with elevated PSA levels ( $PSA \geq 1.5$  ng/ml) and provides tailored recommendations based on their risk assessment:

- If PSA is elevated ( $PSA \geq 1.5$  ng/ml), Stockholm3 is performed. The outcome from the test is the Stockholm3 Risk Score, an integer (no decimals) between 1 and 99 and an accompanying recommendation.

o If Stockholm3 Risk Score is 1-3, a new test is recommended in 6 years.

- o If Stockholm3 Risk Score is 4-10, a new test is recommended in 2 years.
- o If Stockholm3 Risk Score  $\geq$  11, referral to urologist and further diagnostic work-up (in accordance with clinical practice) is recommended.

With a PSA test alone, only patients with a PSA > 3ng/ml are referred for further investigation.

## Proposed MBS items

### Proposed Item AAAAA

#### MBS item number:

66655

#### Please search and select the proposed category:

PATHOLOGY SERVICES

#### Please search and select the proposed group:

CHEMICAL

#### Please search and select the proposed item descriptor or draft a proposed item descriptor to define the population and health technology usage characteristics that would define eligibility for funding:

Prostate cancer risk profiling for men aged 45 to 74 years, without a previous cancer diagnosis and PSA of 1.5ng/ml or greater with a multiparametric blood test, Stockholm3, requested by a medical practitioner practicing in general practice, a specialist or consultant physician.

#### Proposed MBS fee:

\$750.00

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

\$750.00

#### Please specify any anticipated out of pocket costs:

\$187.50

#### Provide details and explain:

The difference between the proposed benefit and the scheduled fee may be an out-of-pocket expense if the service is not bulk-billed. This will be \$187.50 for a 75% benefit and \$112.50 for an 85% benefit.

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

It is not available in Australia at present.

## 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:**

The overall claim is that PSA testing plus Stockholm3 is superior to PSA testing alone in men without prostate cancer aged 45-74 years.

Stockholm3 as a reflex test to PSA  $\geq 1.5$ ng/ml presents an advanced risk assessment tool that can be employed to focus diagnostic procedures on clinically significant prostate cancer (csPC), reducing the overdiagnosis of low-grade cancers and allowing more efficient use of healthcare resources, compared to the current standard use of the PSA test with cut-off 3 ng/ml. These improvements can be achieved without disrupting the current care pathway, altering patient management, causing delays in diagnosis and referral, or necessitating additional medical visits.

The benefits of implementing Stockholm3 in the early diagnosis pathway include:

- Enhanced detection of clinically significant localized prostate cancer, which can result in a better prognosis for affected individuals.
- A reduction in the overdiagnosis of low-grade cancers, preventing unnecessary treatments and emotional stress for patients.
- Fewer cases of metastatic disease diagnosed at advanced stages, increasing the chances of successful treatment.
- Fewer follow-up visits for low-risk individuals, reducing the burden on both patients and the healthcare system.
- Lower resource requirements for follow-up visits and diagnostic procedures, such as MRI scans and prostate biopsies, for low-grade cancers. This leads to reduced healthcare costs and avoids overtreatment.
- Improved precision in the diagnostic workup, resulting in a lower level of stress and anxiety for men aged over 45 years who are concerned about prostate cancer.
- Addressing the need for the diagnosis and care of aggressive prostate cancer in patients with PSA levels between 1.5 to 2.9 ng/ml, who are currently at risk of underdiagnosis due to the accepted PSA with cutoff of 3 ng/ml.
- Overall cost savings in prostate cancer care, benefiting the healthcare system and patients.

## **Estimated utilisation**

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

As of March 2023, the Australian Bureau of Statistics estimated that 33.1% of the Australian male population is aged 45 to 74 which is 4,348,692 males. Theoretically all males aged over 50 and those men with a family history of prostate cancer aged over 45. However, we know that less than half of the eligible population receive a PSA test. This may be for a variety of reasons including:

- Unwillingness to take the test
- Lack of knowledge of the test.
- General practitioner or specialist does not refer for the test.

It may be useful to examine the utilisation of the current MBS item numbers claimed for PSA testing. There are two relevant item numbers:

1. 66654 - Prostate specific antigen – quantitation in the monitoring of high-risk patients. For any particular patient, applicable not more than once in 11 month

There was no utilisation of this item number in financial year 2022-2023. The item number only came into existence on November 1, 2023

2. 66655 -Prostate specific antigen—quantitation. For any particular patient, applicable not more than once in 23 months

In the financial year 2022/23 this item number was utilised a total of 764,533 times of which 593,276 was claimed by patients aged from 45 to less than 75 years. It is anticipated that between REDACTED% of patients will have a PSA  $\geq$  1.5ng/ml. Therefore the likely population is a range between REDACTED (REDACTED%) and REDACTED (REDACTED%)

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

**Year 1 estimated uptake(%):**

REDACTED

**Year 2 estimated uptake(%):**

REDACTED

**Year 3 estimated uptake(%):**

REDACTED

**Year 3 estimated uptake(%):**

REDACTED

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

REDACTED

**Optionally, provide details:**

This number is REDACTED% of the estimated population, which is the highest likely utilisation.

**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):**

30 years

**Optionally, provide details:**

The Stockholm3 may be delivered after a patient turns 45. The test may be delivered until a patient turns 75.

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

Every 2 - 6 years

**Optionally, provide details:**

Repeat Stockholm3 is recommended to patients with low Stockholm3 Risk Score as follows:

-If the Stockholm3 Risk Score is 1-3, a new test is recommended in 6 years.

- If the Stockholm3 Risk Score is 4-10, a new test is recommended in 2 years.
- It is not used in patients with previously diagnosed prostate cancer.

## Consultation

**List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the health technology/service:**

**Professional body name:**

THE ROYAL COLLEGE OF PATHOLOGISTS OF AUSTRALASIA

**List all appropriate professional bodies / organisations representing the group(s) of health professionals who request the health technology/service:**

**Professional body name:**

THE ROYAL AUSTRALIAN COLLEGE OF GENERAL PRACTITIONERS LIMITED

**Professional body name:**

THE UROLOGICAL SOCIETY OF AUSTRALIA AND NEW ZEALAND

**List all appropriate professional bodies / organisations representing the group(s) of health professionals that may be impacted by the health technology/service:**

**Professional body name:**

THE ROYAL AUSTRALIAN COLLEGE OF GENERAL PRACTITIONERS LIMITED

**Professional body name:**

THE ROYAL COLLEGE OF PATHOLOGISTS OF AUSTRALASIA

**Professional body name:**

THE UROLOGICAL SOCIETY OF AUSTRALIA AND NEW ZEALAND

**List the patient and consumer advocacy organisations or individuals relevant to the proposed health technology:**

**Number of organisations listed:** 1

**Professional body name:**

Prostate Cancer Foundation of Australia (PCFA)

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

## 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)?**

No

**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

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

No

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

No