

# **MSAC Application 1788**

## **ArteraAI Prostate Biopsy Assay**

# Application for MBS eligible service or health technology

**ID:**

HPP200203

**Application title:**

ArteraAI Prostate Biopsy Assay

**Submitting organisation:**

REDACTED CONSULTING

**Submitting organisation ABN:**

REDACTED

## Application description

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

The proposed intended use population for the ArteraAI Prostate Biopsy Assay is adult males with intermediate risk localised prostate cancer (as defined by recognised guidelines) without clinically or pathologically defined metastases who will undergo curative-intent therapy. The purpose of the test is to inform the prognosis and help inform treatment decisions regarding use of short-term androgen deprivation therapy. Currently, clinicians rely solely on existing risk assessment tools based on clinical and demographic factors to designate risk classification and to guide treatment decisions.

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

The ArteraAI Prostate Biopsy Assay is a software device based on artificial intelligence that assesses physician-provided clinical variables and whole slide images of prostate needle biopsy specimens prepared from hematoxylin and eosin stained formalin-fixed paraffin-embedded tissue. The test provides grouped and continuous risk estimates of distant metastasis and prostate cancer specific mortality for patients with localised prostate cancer and informs likelihood of benefit from the addition of short-term androgen deprivation therapy for these individuals.

### 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:**

Artera Inc.

## 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:**

Other

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

The ArteraAI Prostate Biopsy Assay is a software device based on artificial intelligence (AI) that assesses physician-provided clinical variables and whole slide images (WSI) of prostate needle biopsy specimens to provide prognosis of risk and predict therapy benefit.

## PICO Set

### ArteraAI Prostate Biopsy Assay for patients with localised prostate cancer

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

**Purpose category:**

Predictive

**Purpose description:**

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

**Purpose category:**

Prognosis

**Purpose description:**

To provide information about prognosis (staging/re-staging)

## Population

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

The proposed patient population for the ArteraAI Prostate Biopsy Assay include men with localised prostate cancer that have an NCCN risk category of intermediate risk (favourable or unfavourable) who are planned to undergo curative-intent radiotherapy for prostate cancer, where intermediate risk is defined as follows:

Has all of the following:

- No high-risk group features
- No very-high-risk group features

- Has one or more intermediate risk factors (IRFs):
  - Clinical stage cT2b-cT2c
  - Grade Group 2 or 3 (Gleason Score 7 [3+4] or Gleason Score 7 [4+3])
  - PSA 10-20ng/mL

Favourable intermediate risk (has all of the following)

- 1 intermediate risk factor (IRF)
- Grade Group 1 or 2 (Gleason Score < 6 or Gleason Score 7 [3+4])
- < 50% biopsy cores positive (e.g., < 6 of 12 cores)

Unfavourable intermediate risk (has at least one of the following):

- 2 or 3 IRFs
- Grade Group 3 (Gleason Score 7)
- ≥ 50% biopsy cores positive (e.g., > 6 of 12 cores)

Where IRFs are as follows:

- Clinical stage cT2b-cT2c
- Grade Group 2 or 3 (Gleason Score 7 [3+4] or Gleason Score 7 [4+3])
- PSA 10-20ng/mL

As per the instructions for use (provided as an attachment), the contraindications for the ArteraAI Prostate Biopsy Assay are as follows:

- Diagnosis of metastatic cancer
- Previous cancer treatment of curative intent

Prior to ArteraAI Prostate Biopsy Assay testing, a diagnosis of prostate cancer must be established on H&E stained histopathology of prostate core needle biopsies.

The initial evaluation for potential prostate cancer is typically conducted by a urologist, prompted by symptoms consistent with prostate cancer or elevated PSA levels in male patients. The urologist performs a prostate biopsy, which involves sampling cores of the prostate. These prostate cores are sent to a pathology laboratory, where each core is stained with hematoxylin and eosin (H&E), which is typically sufficient for diagnosing the presence or absence of prostate cancer and assigning a Gleason score. The diagnosis, including Gleason scores of each core, are communicated back to the referring physician.

Localised prostate cancer is consistent with the cancer being contained within the prostate (stage T1 or T2). Risk classification will help inform management. The proposed population are those that have localised prostate cancer, of intermediate risk and in whom radiation therapy with curative intent is planned. The decision in these patients is whether or not short-term androgen deprivation therapy (ST-ADT) should be used.

The risk stratification is established by urologists or by radiation oncologists. To note, the Urological Society of Australia and New Zealand (USANZ) have endorsed the European Association of Urology (EAU) guidelines for prostate cancer, whereas radiation oncologists managing prostate cancer in Australia align with the NCCN guidelines for risk assessment and management. As discussed elsewhere, broadly speaking, the two guidelines are similar

with respect to risk classification and management recommendations, noting that the EAU guidelines do not stratify intermediate risk patients into favourable and unfavourable which the NCCN guidelines do. The EAU guidelines refer to the NCCN guidelines with respect to treatment recommendations for those with favourable and unfavourable intermediate risk.

Importantly, the work up and lead up to diagnosis of patients will not change as a consequence of the introduction of the proposed test. Notably, the same whole slide images (WSI) of prostate needle biopsy samples used to inform the clinical risk assessment tools as per current standard of care would be used in the ArteraAI Prostate Biopsy Assay.

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

Malignant tumour of prostate

## **Intervention**

**Name of the proposed health technology:**

ArteraAI Prostate Biopsy Assay

## **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 main comparator to the ArteraAI Prostate Biopsy Assay reflect current standard of care (SoC) clinical practice to assess risk of patients with localised prostate cancer, and to inform which patients with intermediate risk should be treated with short term androgen deprivation therapy (ST-ADT). In Australia the National Comprehensive Cancer Network (NCCN) and the European Association of Urology (EAU) risk groupings are used by radiation oncologists and urologists, respectively.

## **Outcomes**

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

A known limitation of the NCCN risk stratification groups (and other risk classification systems) is that they do not discriminate risk sufficiently to direct treatment management within risk strata nor do they predict if treatment with ST-ADT, which induces undesirable adverse effects, is likely or not likely to improve outcomes for a particular patient. Compared with the NCCN risk stratification tool the ArteraAI Prostate Biopsy Assay models have superior discriminatory performance across all morbidity and disease related mortality endpoints: distant metastasis (5 and 10 year), biochemical failure (5 and 10 year), and prostate cancer specific survival (Esteva 2022). Therefore, the test will result in a change in prognosis that will be of value to the patient and the treating clinician.

The results from the ArteraAI Prostate Biopsy Assay will also inform the likelihood that a patient with intermediate risk localised prostate cancer, who is planned for curative intent radiation therapy, will benefit from adjuvant ST-ADT (Gerrard 2024; Spratt 2023). This

information will lead to changes in management, resulting in health benefits, reduced health risks, and resource savings. A forthcoming study, the ASTuTE trial, is a decision impact study that will inform the extent of change in management as a consequence of the ArteraAI Prostate Biopsy Assay (refer to the Summary of Evidence).

## **Proposed MBS items**

### **Proposed Item AAAAA**

**MBS item number:**

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

PATHOLOGY SERVICES

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

TISSUE PATHOLOGY

**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:**

ArteraAI Prostate Biopsy Assay for men with localised prostate cancer that have a National Comprehensive Cancer Network (NCCN) risk category of intermediate risk (favourable or unfavourable), who are planned to undergo curative-intent radiotherapy for prostate cancer, where intermediate risk is defined as follows:

Has all of the following:

No high-risk group features

No very-high-risk group features

Has one or more intermediate risk factors (IRFs):

Clinical stage cT2b-cT2c

Grade Group 2 or 3 (Gleason Score 7 [3+4] or Gleason Score 7 [4+3])

PSA 10-20ng/mL

Favourable intermediate risk: (has all of the following)

1 intermediate risk factor (IRF)

Grade Group 1 or 2 (Gleason Score < 6 or Gleason Score 7 [3+4])

< 50% biopsy cores positive (e.g., < 6 of 12 cores)

Unfavourable intermediate risk (has at least one of the following)

2 or 3 IRFs

Grade Group 3 (Gleason Score 7)

≥ 50% biopsy cores positive (e.g., > 6 of 12 cores)

The artificial intelligence prostate biopsy assay should not be used in patients with a diagnosis of metastatic cancer or those who have previously received cancer treatment of curative intent.

The test may be used once per new prostate cancer diagnosis.

**Proposed MBS fee:**

\$1,200.00

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

\$1,200.00

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

\$98.70

**Provide details and explain:**

Given this is an out of hospital procedure, Medicare will fund 85% of the proposed fee with the patient paying the gap. However, the gap in this instance of \$180 exceeds the greatest permissible gap (GPG), hence the patient will pay the GPG of \$98.70 and Medicare would pay the remainder of \$1,101.30.

The proposed MBS fee for the ArteraAI Prostate Biopsy Assay covers the cost of the test and the fee for the pathologist.

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

No 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:**

Compared to the NCCN risk stratification tool, the ArteraAI Prostate Biopsy Assay models have superior discriminatory performance across all distant metastasis (5 and 10 year), biochemical failure (5 and 10 year), prostate cancer specific survival, improving the value of knowing for patients.

The ArteraAI Prostate Biopsy Assay "biomarker" is predictive of response/benefit of ST-ADT in patients with intermediate risk localised prostate cancer who are intended for radiotherapy with curative intent. The test results will lead to superior health outcomes because it will ensure patients

who are not likely to benefit from ST-ADT treatment can avoid the negative consequences of treatment and those who are likely to benefit will receive treatment with ST-ADT.

## Estimated utilisation

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

According to Australian Institute of Health and Welfare (AIHW), it is estimated that 26,088 new cases of prostate cancer are diagnosed in 2024 (AIHW 2023). Approximately 45% of these cases were diagnosed with NCCN intermediate risk in 2023 and, of those, 25% received radiation therapy with or without androgen deprivation therapy (ADT) (9% with and 16% without ADT, respectively). These proportions are based on data reported by the Prostate Cancer Outcomes Registry Australia and New Zealand (PCOR-ANZ; Ong 2024). Based on the 2024 incidence estimate, approximately 3,000 patients are estimated to be diagnosed with

NCCN intermediate risk prostate cancer AND treated with radiation therapy with or without ADT.

**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:**

**Will the technology be needed more than once per patient?**

No, once only

## **Consultation**

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

- Royal College of Pathologists of Australasia (RCPA)

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

- Royal Australian and New Zealand College of Radiologists (RANZCR)
- Urological Society of Australia and New Zealand (USANZ)

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

- Royal Australian and New Zealand College of Radiologists (RANZCR)
- Urological Society of Australia and New Zealand (USANZ)

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

- Prostate Cancer Foundation of Australia (PCFA)

## **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?**

Class III

**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