

## **MSAC Application 1765**

**Amendment of MBS items 73303 and 73304 (BRCA1/2 mutation testing in patients with metastatic castration resistant prostate cancer) to include talazoparib**

# Application for MBS eligible service or health technology

**MSAC Application Number:**

1765

**Application title:**

Amendment of existing MBS items 73303 and 73304 (BRCA1/2 mutation testing in patients with metastatic castration resistant prostate cancer) to include talazoparib

**Submitting organisation:**

PFIZER AUSTRALIA PTY LTD

**Submitting organisation ABN:**

50008422348

## Application description

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

In Australia, it is estimated that prostate cancer will be the most commonly diagnosed cancer in males, with an estimated 24,217 new cases and 3,507 deaths in 2022. On average, prostate cancer in males is diagnosed before Stage II, and in 2011, 4.2% of total prostate cancer cases were diagnosed at metastatic disease (Stage IV). In 2011, prostate cancer had close to 100% 5-year relative survival when diagnosed at Stage I. At Stage IV, the 5-year relative survival rate fell to 36% (Australian Institute of Health and Welfare, 2019).

Prostate cancer is termed 'castrate resistant' when the disease progresses despite continuous androgen deprivation therapy. This application concerns the metastatic disease stage of prostate cancer, which constitutes a small proportion of the overall disease and additionally targeting a subgroup of patients with genetic mutations in their homologous recombination repair (HRR) genes. BRCA 1 and BRCA 2.

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

The medical service is an existing diagnostic test on the MBS. Testing of prostate tumour tissue (somatic) and germline to detect BRCA1/2 (BRCA1/2 gene) gene mutations is performed in men with metastatic castration-resistant prostate cancer (mCRPC) to determine their eligibility for treatment with PBS-listed olaparib.

BRCA testing is well established in Australia and is currently performed in mCRPC, as well as in breast and ovarian cancer. It is performed by many public and private pathology laboratories in Australia. It is unlikely that a patient would require more than one tumour BRCA1/2 test in their lifetime.

## 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

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

Yes

## 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 Prosthesis List?**

Yes

**Which list/schedule will the other health technologies be listed on?**

Pharmaceutical Benefits Scheme

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

Amendment

**What is the nature of the amendment?**

Minor amendment to the item descriptor that does not affect how the service is delivered.

**Justification for amendment:**

To change the description of Medicare Benefits Scheme (MBS) item 73303 and 73304 to add talazoparib, a new treatment option for patients with metastatic castration resistant prostate cancer, to the listing. MBS item 73303 is for the testing of tumour tissue for BRCA gene variants from patients with metastatic castration resistant prostate cancer (mCRPC); MBS item 73304 enable testing for germline BRCA gene variants in patients with mCRPC for whom tumour testing is not possible. These two genetic tests are required to determine eligibility for clinically appropriate access to treatment with PBS-listed olaparib. MSAC has already accepted the comparative safety, clinical effectiveness and cost-effectiveness for this type of genetic testing for olaparib in mCRPC. This application requests the addition of talazoparib, a new treatment option for patients with mCRPC, to the test (talazoparib and olaparib belong to the same therapeutic class of medicines, PARP inhibitors).

**Please select any relevant MBS items:**

MBS item number	Selected reason type
73303	Expansion or amendment to existing item
73304	Expansion or amendment to existing item

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

Investigative

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

Molecular diagnostic tests

**Please select the type of molecular diagnostics health technology:**

Small panel gene assay

## PICO Set

**Adult patients with metastatic castration-resistant prostate cancer with evidence of BRCA1/2 genetic variant and who have not previously been treated with a novel hormonal agent. Intervention: Talazoparib (0.5 mg) in combination with enzalutamide (160 mg)**

**Purpose category:**

Predictive

**Purpose description:**

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

## Population

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

Adult patients with metastatic castration-resistant prostate cancer with evidence of BRCA1/2 genetic variant and who have not previously been treated with a novel hormonal agent.

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

mCRPC

## Intervention

**Name of the proposed health technology:**

Talazoparib (0.5 mg) in combination with enzalutamide (160 mg)

## 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:**

Main comparator: Enzalutamide monotherapy

Supplementary comparator 1: olaparib + abiraterone

Supplementary comparator 2: abiraterone monotherapy

## Outcomes

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

Primary outcome:

- Radiographic progression-free survival (rPFS) by blinded independent central review (BICR)

Key secondary outcome:

- Overall survival

Secondary outcomes:

- Objective response rate
- Time to treatment discontinuation
- Time to second progression-free survival
- Safety
- Quality-of-life

## Proposed MBS items

### Proposed Item AAAAA

**MBS item number:**

73303

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

PATHOLOGY SERVICES

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

GENETICS

**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:**

A test of tumour tissue from a patient with metastatic castration-resistant prostate cancer, including subsequent characterisation of germline gene variants should tumour tissue testing undertaken during the same service be inconclusive, requested by a specialist or consultant physician, to determine eligibility relating to BRCA status for access to olaparib or talazoparib under the Pharmaceutical Benefits Scheme. Applicable once per primary tumour diagnosis

**Proposed MBS fee:**

\$1,000.00

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

\$1,000.00

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

\$250.00

**Provide details and explain:**

The current cost of the BRCA mutation test for MBS item 73303 (tumour testing) and MBS item 73304 (germline testing) is \$1000 per test. Changing these two MBS items to add talazoparib will not change the cost to the MBS. Only one test is required per lifetime.

### Proposed Item BBBB

**MBS item number:**

73304

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

PATHOLOGY SERVICES

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

GENETICS

**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:**

Detection of germline BRCA1 or BRCA2 pathogenic or likely pathogenic gene variants, in a patient with metastatic castration-resistant prostate cancer, for whom testing of tumour tissue is not clinically feasible, requested by a specialist or consultant physician, to determine eligibility for olaparib or talazoparib under the Pharmaceutical Benefits Scheme. Applicable once per lifetime.

**Proposed MBS fee:**

\$1,000.00

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

\$1,000.00

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

\$250.00

**Provide details and explain:**

The current cost of the BRCA mutation test for MBS item 73303 (tumour testing) and MBS item 73304 (germline testing) is \$1000 per test. Changing these two MBS items will not change the cost to the MBS. Only one test is required per lifetime.

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

MBS funded. This application seeks an amendment to MBS Item 73303 and MBS item 73304 to add access to talazoparib (a PARP inhibitor) under the Pharmaceutical Benefits Scheme. The change will not result in a change to testing methodology, the patient population who access testing through the MBS, or to the MBS fee.

## 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:**

**Efficacy:**

A clinical claim of superior efficacy is made for talazoparib plus enzalutamide versus placebo plus enzalutamide based on data from the pivotal Phase 3 TALAPRO-2 randomised controlled trial that demonstrated that talazoparib plus enzalutamide resulted in clinically meaningful and statistically significant improvement in primary endpoint of radiographic progression-free survival versus standard of care enzalutamide as first-line treatment for patients with BRCA1/2 gene mutations.

**Safety:**

Talazoparib plus enzalutamide has an inferior safety profile to placebo plus enzalutamide, with this being regarded as tolerable and manageable, as evidenced by no detriment to quality of life.

## Estimated utilisation

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

Data obtained from AIHW 'Cancer Data in Australia' estimated that 24,217 new cases of prostate cancer were diagnosed in Australia in 2022. A systematic review of CRPC epidemiology (Kirby et al, 2011) reports a range of 10% to 20% of men with prostate cancer will progress to castration resistant prostate cancer within 5 years. The study population in the UK Health Information Network (THIN) appears most relevant to this application (11.2% of patients diagnosed with prostate cancer developed castrate resistant cancer within 5 years). A small Japanese study (Wade et al, 2018) reports that  $\geq 84\%$  of patients will have metastases at the time of CRPC diagnosis. A Spanish study (de Velasco et al 2022) reports the prevalence of patients with mCRPC is 12.1%.

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

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

70.2

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

70.2

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

70.2

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

70.2

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

2278

### **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:**

#### **Professional body name:**

The Royal College of Pathologist of Australasia

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

#### **Professional body name:**

n/a

### **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:**

n/a

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

**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:**

**Professional body name:**

n/a

## **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

## **Co-dependent details**

**Will a submission be made to the Pharmaceutical Benefits Advisory Committee (PBAC)?**

Yes

**Please provide a rationale for the co-dependency and indicate how the proposed PBS restriction would reference the intervention(s) proposed for MSAC consideration:**

The amendment of BRCA1/2 mutation testing on the MBS to allow access to talazoparib treatment on the Pharmaceutical Benefits Scheme (PBS) would present a new approach towards the management of adult patients with metastatic castration resistant prostate cancer with evidence of BRCA1/2 gene variants.