

## **MSAC Application 1783**

**Genetic testing to detect PIK3CA mutations in patients with hormone receptor (HR)-positive, HER-2 negative, locally advanced or metastatic breast cancer, to determine eligibility for treatment with PBS subsidised inavolisib**

# Application for MBS eligible service or health technology

**ID:**

HPP200163

**Application title:**

Genetic testing to detect PIK3CA mutations in patients with hormone receptor-positive, HER-2 negative, locally advanced or metastatic breast cancer to help determine eligibility for inavolisib

**Submitting organisation:**

ROCHE PRODUCTS PTY LTD

**Submitting organisation ABN:**

70000132865

## Application description

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

This application is for a pathology test to detect the PIK3CA mutation in hormone receptor positive, HER2 receptor negative advanced or metastatic breast cancer patients who have relapsed during or after endocrine therapy.

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

The pathology test would detect the presence of PIK3CA mutations in tumor material (tissue or blood) to confirm eligibility for a new treatment PBS listed in Australia for advanced or metastatic breast cancer.

## 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 Prescribed 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?**

New

**Please select any relevant MBS items.**

MBS item number	Selected reason type
-----------------	----------------------

**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:**

Single gene assay

## PICO Sets

**Application PICO sets**

PICO set number	PICO set name
1	Inavolisib for PIK3CA mutated HR+, HER2-, locally advanced or metastatic breast cancer

## Inavolisib for PIK3CA mutated HR+, HER2-, locally advanced or metastatic breast cancer

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

**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

## Population

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

Adults ( $\geq 18$  years of age) with hormone receptor-positive (HR+), HER2-negative (HER2-) locally advanced or metastatic breast cancer.

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

Malignant neoplasm of breast

## Intervention

### **Name of the proposed health technology:**

Testing for PIK3CA mutation status using a next generation sequencing (NGS) 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:**

Comparators are nominated for the PIK3CA testing and inavolisib components:

- For the PIK3CA testing component, the nominated comparator is no PIK3CA testing
- For the inavolisib component, the nominated comparator is palbociclib plus fulvestrant.

## Outcomes

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

Major outcome: Progression free survival

Major outcome: Overall survival

Minor outcome: Objective response rate

Minor outcome: Best overall response

Minor outcome: Duration of response

Minor outcome: Clinical benefit rate

Major outcome: Rate and nature of adverse events reported in patients treated with inavolisib in combination with palbociclib plus fulvestrant vs placebo in combination with palbociclib plus fulvestrant.

A change in management is expected as a result of the test information. Patients identified as harbouring a PIK3CA mutation would be eligible for treatment with inavolisib (used in combination with palbociclib plus fulvestrant). Patients with no PIK3CA mutations identified would not be eligible for inavolisib and, subsequently, managed with palbociclib plus fulvestrant or other CDK 4/6 inhibitor plus fulvestrant or aromatase inhibitor based on individual patient circumstances.

## 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:**

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:**

Next generation sequencing (NGS) test for phosphatidylinositol 4,5-bisphosphate 3-kinase catalytic subunit alpha isoform (PIK3CA) mutations performed on tumour tissue or circulating tumour DNA (ctDNA) from a patient with locally advanced (inoperable) or metastatic breast cancer, if:

(a) The breast cancer is documented as hormone receptor-positive; and

(b) The breast cancer is documented as HER2-negative; and

(c) The test is requested by a specialist or consultant physician to determine if requirements relating to PIK3CA mutation status for access to a PIK3CA inhibitor under the Pharmaceutical Benefits Scheme are fulfilled

Applicable only once per lifetime

**Proposed MBS fee:**

\$400.00

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

\$400.00

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

\$0.00

**Provide details and explain:**

PIK3CA testing is currently being offered by several private and public molecular pathology laboratories at a fee of \$350 - \$400. A MBS funded item in the same price range will minimize the potential for out of pocket expenses.

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

PIK3CA testing in breast cancer patients is currently being undertaken in several private and public molecular pathology laboratories. Under these arrangements, testing would either be self-funded by patients or funded through State-based programs.

For patients being managed in clinics registered as investigational sites for breast cancer clinical trials, PIK3CA testing may be performed through research funding or supported by the sponsor of the clinical trial.

## 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 PIK3CA testing followed by inavolisib in combination with palbociclib and fulvestrant in patients with PIK3CA mutations is superior to no PIK3CA testing and treatment with palbociclib plus fulvestrant.

The clinical claim is supported by the results of the INAVO120 trial where improvements in

progression free survival and overall survival were reported for patients treated with inavolisib. All patients enrolled in the INAVO120 trial were assessed as having PIK3CA mutations by testing of tumour tissue or ctDNA.

## Estimated utilisation

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

The AIHW estimates 20,771 Australians will be diagnosed with breast cancer in 2024 with a projected long-term incidence of around 2% each year (AIHW Cancer Data 2023). The Australian Metastatic Breast Circulating Biomarker study reports 78% of metastatic breast cancers involve the HR-positive, HER2-negative subtype (Bujak 2020). It is estimated that approximately 25% of breast cancer patients will relapse after surgery and adjuvant therapy (Gonzalez Hurtado 2023); and approximately 30% of relapsed patients will have primary or secondary endocrine resistance (Hartkopf 2020).

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

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

100

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

100

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

100

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

100

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

1215

### **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:**

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

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:**

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

Medical Oncology Group of Australia (MOGA)

**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:**

To be confirmed

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

**Number of organisations listed: 1**

**Professional body name:**

Breast Cancer Network Australia (BCNA)

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

**Professional body name:**

Illumina

**Professional body name:**

Roche Diagnostics

**Professional body name:**

ThermoFisher Scientific

## **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

## Codependent details

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

Yes

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

Roche is submitting to the PBAC an application for reimbursement of inavolisib. Inavolisib selectively inhibits proliferation and induces apoptosis in PIK3CA-mutant breast cancer cell lines. In the INAVO120 trial patients with the PIK3CA mutation were enrolled to receive inavolisib plus palbociclib plus fulvestrant versus placebo plus palbociclib plus fulvestrant. The proposed PBS restriction would require eligible patients to receive inavolisib who have a PIK3CA mutation detected by an NGS assay available in Australian pathology laboratories.