MSAC Application 1766

Genetic testing to detect AKT-pathway alterations in patients with hormone receptor-positive, HER2-negative advanced breast cancer, to determine eligibility for PBS subsidised capivasertib treatment

Application for MBS eligible service or health technology

MSAC Application Number:
1766

Application title:
Genetic testing to detect AKT-pathway alterations in patients with hormone receptor-positive, HER2-negative advanced breast cancer, to determine eligibility for PBS subsidised capivasertib treatment.

Submitting organisation:
ASTRAZENECA PTY LTD

Submitting organisation ABN:
54009682311

Application description

Succinct description of the medical condition/s:
HR-positive/HER2-negative recurrent, unresectable, or metastatic breast cancer who have relapsed on endocrine therapy. One of the mechanisms of resistance to endocrine therapy is the activation of the AKT Pathway (PIK3CA/AKT/PTEN), a signalling pathway causing tumour growth, and relapse of disease. AKT Pathways activation includes:

- Activating mutations in PIK3CA or AKT1 which can inappropriately activate the pathway.
- Loss of function mutations in PTEN which can lead to unregulated signalling.

Succinct description of the service or health technology:

The application is to request public funding for the testing of AKT-pathway alterations (PI3KCA, AKT1 or PTEN) by Next Generation Sequencing (NGS) in tumour tissue from patients with locally advanced (inoperable) or metastatic HR-positive/HER2-negative (HR+/HER2-) breast cancer following recurrence or progression on or after aromatase inhibitor therapy, with or without a CDK4/6 inhibitor.

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?
Not sure

Please select any relevant MBS items.
-

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:
Whole exome/genome sequencing

PICO Set

Capivasertib in HR+/HER2- advanced breast cancer

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

Purpose category:
Diagnosis / sub-classification

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

Population

Describe the population in which the proposed health technology is intended to be used:
Patients with locally advanced (inoperable) or metastatic HR-positive/HER2-negative (HR+/HER2-) breast cancer following recurrence or progression on or after aromatase inhibitor therapy, with or without a CDK4/6 inhibitor.

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

Intervention

Name of the proposed health technology:
Capivasertib + fulvestrant

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:
No comparator

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:
The addition of capivasertib to fulvestrant significantly improved PFS in patients with AI-resistant HR+/HER2– advanced breast cancer in the overall population, with a more pronounced benefit in pathway altered tumours.

Proposed MBS items

Proposed Item AAAAA

MBS item number:
-

Proposed category:
PATHOLOGY SERVICES

Proposed group:
TISSUE PATHOLOGY

Proposed item descriptor:
A test of tumour tissue for the detection of an AKT-pathway altered (PIK3CA, AKT1 or PTEN) tumour, in a patient with locally advanced (inoperable) or metastatic hormone receptor positive, HER2-negative breast cancer

As requested by a specialist or consultant physician, to determine eligibility for treatment with an AKT serine/threonine kinase -inhibitor under the Pharmaceutical Benefits Scheme

Maximum of one test per patient's lifetime.

Proposed MBS fee:
$0.01

Indicate the overall cost per patient of providing the proposed health technology:
$0.01

Please specify any anticipated out of pocket costs:
$0.01

Provide details and explain:
The true cost of the current test is unknown.

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

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:
Currently for patients with AKT-pathway altered (PIK3CA, AKT1, PTEN) tumour and HR-positive, HER2-negative advanced breast cancer, treatments are not targeted so typically involve alternative therapeutic agents that a patient has not been exposed to.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:
A detailed utilisation analysis will be presented in the integrated co-dependent MSAC/PBAC submission.

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:
000

Optionally, provide details:
A detailed utilisation analysis will be presented in the integrated co-dependent MSAC/PBAC submission.

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:

- Medical Oncology Group of Australia (MOGA)
- Royal Australasian College of Physicians (RACP)
- Royal Australasian College of Surgeons (RACS)

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

- Royal College of Pathologists of Australasia (RCPA)

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

- 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:

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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?
No

Co-dependent 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:
The application is to request public funding for the testing of AKT-pathway alterations (PI3KCA, AKT1 or PTEN) by Next Generation Sequencing (NGS) in tumour tissue from patients with locally advanced (inoperable) or metastatic HR-positive/HER2-negative (HR+/HER2-) breast cancer following recurrence or progression on or after aromatase inhibitor therapy, with or without a CDK4/6 inhibitor.

It is proposed to be a diagnostic service for eligibility for capivasertib + fulvestrant treatment in patients with confirmed AKT-pathway altered (PIK3CA, AKT1 or PTEN) tumour and locally advanced or metastatic HR+/HER2- breast cancer.

In CAPItello-291, the addition of capivasertib to fulvestrant significantly improved PFS in patients with AI-resistant HR+/HER2– advanced breast cancer in the overall population, with a more pronounced benefit in pathway altered tumours (Turner et al 2023).

Capivasertib is currently undergoing TGA evaluation for treatment in this population.