MSAC application 1816

Genetic testing to detect estrogen receptor 1 (ESR1) variants in patients with hormone receptor (HR)-positive, HER-2 negative, locally advanced or metastatic breast cancer to determine eligibility for treatment with PBS subsidised camizestrant

Application for MBS eligible service or health technology

HPP Application number:

HPP200356

Application title:

Genetic testing to detect ESR1 mutation in locally advanced or metastatic breast cancer to determine eligibility for treatment with camizestrant

Submitting organisation:

ASTRAZENECA PTY LTD

Submitting organisation ABN:

54009682311

Application description

Succinct description of the medical condition/s:

Newly diagnosed, locally advanced or metastatic HR-positive, HER2-negative breast cancer with an activating ESR1 mutation which has been treated with first line CDK 4/6 inhibitor in combination with an aromatase inhibitor for at least 6 months and has not progressed clinically or radiographically.

Succinct description of the service or health technology:

The application is to request public funding for testing to identify ESR1 activating mutations in patients with newly diagnosed locally advanced or metastatic HR-positive, HER2-negative breast cancer who have received first line treatment with a CDK 4/6 inhibitor in combination with an aromatase inhibitor, for at least 6 months, and whose disease has not progressed clinically or radiographically.

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

Applicant organisation name:

ASTRAZENECA PTY LTD

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

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:

Single gene assay

PICO sets

Application PICO sets:

Genetic testing to detect ESR1 mutations in patients with newly diagnosed locally advanced or metastatic HR-positive, HER2-negative breast cancer who have received first line treatment with a CDK 4/6 inhibitor in combination with an aromatase inhibitor, for at least 6 months, and whose disease has not progressed clinically or radiographically, to determine eligibility for camizestrant treatment.

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 newly diagnosed locally advanced or metastatic HR-positive, HER2-negative breast cancer with an activating ESR1 mutation who have received first line treatment with a CDK 4/6 inhibitor in combination with an aromatase inhibitor for at least 6 months, and who disease has not progressed clinically or radiographically.

Select the most applicable Medical condition terminology (SNOMED CT):

Locally advanced breast cancer

Intervention

Name of the proposed health technology:

Test: Testing for ESR1 mutations in ctDNA extracted from blood (liquid biopsy) to determine eligibility for treatment with camizestrant, a novel selective oestrogen receptor degrader (SERD).

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:

Test: No testing, as ESR1 mutation testing is not currently MBS listed

Outcomes

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

Patients who test positive for ESR1 mutations, may be eligible to receive PBS subsidised camizestrant. The SERENA 6 study showed patients who switched from aromatase inhibitor to camizestrant experienced a statistically significant improvement in progression free survival and a decrease in risk of deterioration in patient reported breast cancer symptoms and functioning.

Proposed MBS items

Proposed item:

AAAAA

MBS item number (where used as a template for the proposed item):

NA

Category number:

PATHOLOGY SERVICES

Category description:

Tissue Pathology

Proposed item descriptor:

Testing for ESR1 mutations in ctDNA extracted from blood (liquid biopsy) in patients with locally advanced or metastatic HR-positive, HER2-negative breast cancer who have received at least 6 months of therapy with a CDK 4/6 inhibitor in combination with an aromatase inhibitor and who disease has not progressed clinically or radiographically. As requested by a specialist to determine eligibility for treatment with camizestrant, under the Pharmaceutical Benefits Scheme

Proposed MBS fee:

The MBS fee is TBC, but it is estimated that the fees could be $1,200 (small NGS panel) and $400 (ddPCR). This is consistent with figures referenced in the PICO for MSAC application 1782 (page 17, 1782 Ratified PICO Confirmation, August 2024 PASC meeting)

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

TBC

Please specify any anticipated out of pocket expenses:

TBC

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

Currently, any testing for ESR1 mutations in ctDNA extracted from blood is self-funded by patients.

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:

Testing for ESR1 mutations in ctDNA extracted from blood (liquid biopsy) + camizestrant in combination with a CDK 4/6 inhibitor is superior to no testing + SoC CDK 4/6 inhibitor in combination with an aromatase inhibitor.

Estimated utilisation

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

A detailed utilisation analysis will be presented in the integrated co-dependent 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 4 estimated uptake (%):

100

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

A detailed utilisation analysis will be presented in the integrated co-dependent submission.

Will the technology be needed more than once per patient?

Yes

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

TBC in submission

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

Up to 6 times per year

Optionally, provide details:

Up to 6 times per year, conducted at the same time as routine blood/imaging tests

Consultation

List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.

Entity who provides the health technology/service:

Royal College of Pathologists of Australasia (RCPA)

Entities who request the health technology/service:

Breast Cancer Triallists (BCT)

Medical Oncology Society of Australia (MOGA)

Royal Australasian College of Physicians (RACP)

Royal Australasian College of Surgeons (RACS)

Entity who may be impacted by the health technology/service:

Royal College of Pathologists of Australasia (RCPA)

Patient and consumer advocacy organisations relevant to the proposed service/health technology:

Breast Cancer Network Australia (BCNA)

Metastatic Breast Cancer (MBC) Action Australia

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

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:

The application is to request public funding for the testing of ESR1 mutations in ctDNA extracted from blood (liquid biopsy) from patients with newly diagnosed locally advanced or metastatic HR-positive, HER2-negative breast cancer who have received first line treatment with a CDK 4/6 inhibitor in combination with an aromatase inhibitor for at least 6 months, and who disease has not progressed clinically or radiographically.

It is proposed to be a diagnostic service to determine eligibility for camizestrant + CDK 4/6 inhibitor treatment in patients with confirmed ESR1 mutations and newly diagnosed locally advanced or metastatic HR-positive, HER2-negative breast cancer. In the pivotal SERENA-6 trial, the switch from aromatase inhibitor to camizestrant significantly improved PFS in this patient population. Camizestrant is currently undergoing TGA evaluation for treatment in this population.