

MSAC Application 1787

Immunohistochemistry testing of solid tumour tissue to determine folate receptor alpha (FR α) expression status in adults with platinum-resistant ovarian cancer, for access to PBS ElahereTM (mirvetuximab soravtansine)

Application for MBS eligible service or health technology

ID:

HPP200196

Application title:

Immunohistochemistry testing of solid tumour tissue to determine folate receptor alpha (FR α) expression status in adults with platinum-resistant ovarian cancer, for access to PBS

Submitting organisation:

ABBVIE PTY LTD

Submitting organisation ABN:

48156384262

Application description

Succinct description of the medical condition/s:

Advanced epithelial ovarian, primary peritoneal, or fallopian tube cancer that has relapsed and is considered to be resistant to platinum-based treatment.

Succinct description of the service or health technology:

The submission requests the MBS listing of a test which will measure FR α protein levels in ovarian cancer tumours and determine eligibility for a treatment targeted towards this protein.

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

What is the type of service or health technology?

Therapeutic

PICO Set

Immunohistochemistry testing of solid tumour tissue to determine folate receptor alpha (FR α) expression status in adults with platinum-resistant ovarian cancer, for access to PBS Elahere™ (mirvetuximab soravtansine)

Population

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

Ovarian cancer is the leading cause of death from gynecological cancers globally, and in Australia has the highest death rate at 4.8% of all female cancers per year. There are currently no recommended screening tests for ovarian cancer and the absence of definitive symptoms makes it difficult to diagnose in the early stages; at the time of diagnosis women are typically in advanced stage disease leading to the poor five-year survival rate of just 48% (ACRF 2024).

Ovarian cancer can be classified in two histological subtypes, epithelial and non-epithelial, with 90% of all ovarian cancer epithelial in origin (Reid et al 2017). For patients diagnosed with advanced epithelial ovarian cancer, treatment goals are to maximize or maintain health-related quality of life, while attempting to control disease or minimize further progression. There is no cure for these patients and the standard of care for newly diagnosed women with advanced stage epithelial ovarian cancer is cytoreductive surgery and platinum-based chemotherapy, followed by Poly-ADP ribose polymerase inhibitors (PARPis), such as olaparib, which have been incorporated as recommended maintenance therapy options after first-line (1L) chemotherapy in a subset of patients with pathogenic BRCA gene 1 and 2 mutations. Although most patients initially respond to platinum-based treatment, up to 80% of patients experience disease recurrence, and nearly all patients with recurrent disease will eventually develop platinum resistance for which the prognosis is poor (Lokadasan et al 2016; Davis et al 2014). There remains an urgent need to address the significant unmet need for these patients.

Folate receptor alpha (FR α) is a protein that is expressed in nearly all ovarian cancers and is both a predictive biomarker and a novel therapeutic target (Scaranti et al 2020).

Mirvetuximab soravtansine is a FR α -directed antibody and microtubule inhibitor conjugate with a unique ability to specifically target FR α , which is overexpressed in ovarian cancer solid tumours and minimally expressed by healthy tissue. Mirvetuximab soravtansine is proposed to be funded for adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer (PROC) whose tumours have a high level of FR α expression, also referred to as "FR α -positive". The FR α -positive expression status may be determined using a validated immunohistochemistry (IHC) assay to detect the percentage of viable tumour cells from with membrane staining for FR α , with the clinical cut-off being $\geq 75\%$ tumour cells on a validated IHC test.

This application proposes IHC testing for FR α expression status to determine PBS eligibility for mirvetuximab soravtansine in adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer whose tumours are FR α -positive.

Search and select the most applicable Medical condition terminology (SNOMED CT):
363443007

Intervention

Name of the proposed health technology:

Test: Ventana FOLR1 (FOLR1-2.1) RxDx Assay. Treatment: Elahere™ (mirvetuximab soravtansine).

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 comparator: "No testing", as testing for FR α is not currently funded, nor available or part of the current treatment algorithm.

Treatment comparator: Non-platinum containing, single-agent systemic chemotherapy (paclitaxel, pegylated liposomal doxorubicin or topotecan). There is no recommendation of one specific chemotherapy. The choice of non-platinum containing chemotherapy is dependent on patient characteristics, previous treatment and clinician and patient choice.

Outcomes

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

The test is a predictive companion diagnostic. As a result of a positive FR α test, a change in clinical management would occur. Patients would be eligible to receive mirvetuximab soravtansine on the PBS, resulting in improved health outcomes such as increased progression-free survival, overall survival and maintenance of quality of life.

Test outcomes

- Analytical validity
- Clinical validity
- Clinical utility

Drug outcomes

- Safety and tolerability, including adverse events
- Effectiveness, including overall survival, progression-free survival, response rates, quality of life

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:

A test of tumour tissue for the detection of FR α tumour expression, in a patient with:

- platinum-resistant ovarian cancer

As requested by a specialist or consultant physician, to determine eligibility for treatment with mirvetuximab soravtansine under the Pharmaceutical Benefits Scheme (PBS)

Proposed MBS fee:

\$74.50

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

\$0.00

Please specify any anticipated out of pocket costs:

\$0.00

Provide details and explain:

As a placeholder, the proposed MBS fee is based on comparable IHC item 72814 for PD-L1 testing, to be confirmed through submission process.

A detailed analysis will be presented in the co-dependent MSAC/PBAC submission.

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

Not currently funded.

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:

FR α testing and treatment with mirvetuximab soravtansine is superior when compared to no testing and standard of care treatment (chemotherapy), as supported by the trial evidence and will be demonstrated in the full MSAC/PBAC submission.

Estimated utilisation

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

- Based on AIHW data, the incidence of ovarian cancer (inclusive of fallopian tube and peritoneum) is 13.5 cases per 100,000 females, which would equate to 1,833 cases based on the 2024 population.

- It is also estimated that 90% of cases are epithelial and 65% are diagnosed at Stage III/IV (Cancer Council; NCI 2017 SEER data).
- Therefore the incidence of advanced epithelial ovarian cancer would reflect roughly 1,100 patients.

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:

- Out of the 1,100 advanced epithelial cancer patients estimated above, approximately 70% (770) of these will go on to receive treatment (Beachler et al 2020). If we assume all of these patients have the opportunity to receive FRA testing, REDACTED patients would utilise the test in Year 1 (REDACTED %).
- Future testing patterns for FRA are not yet well understood, given this will be a new biomarker and test within the Australian treatment landscape. Therefore, the above estimate is provided only as an indication. AbbVie will provide a detailed analysis of utilisation estimates within the MSAC/PBAC submission, which will include sensitivity analyses and consider the impact and likelihood of testing occurring at various stages of the patient journey.

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:

- THE ROYAL COLLEGE OF PATHOLOGISTS OF AUSTRALASIA

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

- MEDICAL ONCOLOGY GROUP OF AUSTRALIA
- THE ROYAL AUSTRALIAN AND NEW ZEALAND COLLEGE OF OBSTETRICIANS AND GYNAECOLOGISTS

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

- OVARIAN CANCER AUSTRALIA LIMITED

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

- ROCHE DIAGNOSTICS AUSTRALIA PTY LIMITED

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

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:

REDACTED

The application has been submitted as codependent given that the proposed MBS item is expected to be used to determine eligibility for a treatment on the PBS (mirvetuximab soravtansine).

The proposed PBS restriction will be outlined in detail in the MSAC/PBAC restriction and will be subject to consultation with clinicians. However, it is anticipated that the Clinical criteria of any future PBS restriction would state that mirvetuximab soravtansine treatment is for use in patients with high FRa expression, as confirmed by a validated test. This would be in line with other PBS-listings that rely on MBS-listed tests.