

MSAC Application 1779

Testing of tumour tissue to detect FGFR2 fusions or rearrangements in people with cholangiocarcinoma, to determine eligibility for treatment with PBS subsidised futibatinib

Application for MBS eligible service or health technology

ID:

HPP200172

Application title:

Testing to detect FGFR2 fusion or rearrangement in patients with locally advanced or metastatic cholangiocarcinoma, to determine PBS eligibility for futibatinib

Submitting organisation:

ARTEM HEALTH PTY LTD

Submitting organisation ABN:

87638317870

Application description

Succinct description of the medical condition/s:

Cholangiocarcinoma (CCA) is a rare type of cancer that develops in the bile ducts of the body. The bile ducts are a group of thin tubes that carry bile (a digestive fluid) from the liver and gallbladder to the intestines.

Succinct description of the service or health technology:

Testing to detect fibroblast growth factor receptor 2 (FGFR2) fusions or rearrangements in patients with locally advanced or metastatic cholangiocarcinoma (CCA), to determine Pharmaceutical Benefits Scheme (PBS) eligibility for futibatinib (Lytgobi).

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?

Consultant

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?

No

Applicant Organisation Details**Australian Business Number (ABN):****Applicant organisation name:**

Taiho Pharma Oceania 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

Please select any relevant MBS items.

MBS item number	Selected reason type
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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:

Other genetic test

PICO Sets

Application PICO sets

PICO set number	PICO set name
1	Testing to detect FGFR2 fusion or rearrangement in patients with locally advanced or metastatic cholangiocarcinoma, to determine PBS eligibility for futibatinib

Testing to detect FGFR2 fusion or rearrangement in patients with locally advanced or metastatic cholangiocarcinoma, to determine PBS eligibility for futibatinib

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

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:

This application requests Medicare Benefits Schedule (MBS) listing for testing to detect fibroblast growth factor receptor 2 (FGFR2) fusions or rearrangements in patients with locally advanced or metastatic cholangiocarcinoma (CCA), to determine Pharmaceutical Benefits Scheme (PBS) eligibility for futibatinib (Lytgobi). Cholangiocarcinoma (CCA) is a heterogeneous group of neoplasms of the bile ducts and represents the second most common hepatic cancer after hepatocellular carcinoma (HCC). The incidence of CCA in Australasia has been reported as 0.3 to 3.5 cases per 100,000 population and it is understood that CCA affects approximately 1,300 Australians each year. CCA still shows a high mortality rate due to its aggressiveness, late diagnosis, and immunoregulation capacity. It is rarely diagnosed at an early stage owing to its silent clinical course, lack of biomarkers, difficult-to-access anatomical location, and highly desmoplastic and paucicellular nature. CCA is associated with a dismal median overall survival (OS) of less than 12 months and a 5-year OS of less than 5%. The burden of CCA is steadily growing with increasing incidence worldwide and, despite advances in the understanding of CCA's pathogenetic mechanisms, there are limited therapeutic options available to patients and prognosis remains invariably poor.

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

Metastatic cholangiocarcinoma

Intervention

Name of the proposed health technology:

Test: FGFR2 fusion or rearrangement testing by NGS in tumour tissue sample. FGFR2 fusion or rearrangement testing by FISH in tumour tissue sample can also be considered as an option for testing likely to occur outside of centres with NGS capability. Treatment: Futibatinib 20 mg orally daily until unacceptable toxicity or disease progression.

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: The nominated comparator is 'no testing'.

Treatment: Standard of care subsequent-line therapy, noting that guidelines (ESMO, NCCN) recommend FOLFOX as a preferred regimen for 'all comers'.

It is noted that Application 1750 (Testing of tumour tissue to detect IDH1 mutations in patients with cholangiocarcinoma to determine eligibility for ivosidenib on the PBS) nominated palliative care as a primary comparator, which was accepted in the Ratified PICO. The sponsor would appreciate feedback from the Committee with regard to the relevance of palliative care for this application.

Outcomes

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

Test outcomes: Sensitivity, specificity, positivity predictive value (PPV), negative predictive value (NPV)

Treatment outcomes: OS, PFS, ORR (study primary outcome), DOR, DCR, PROs, safety

Health care system: Cost effectiveness of testing and treatment, financial implications

Testing patients with locally advanced or metastatic CCA for FGFR2 fusion or rearrangement is expected to lead to a change in clinical management, as patients with a positive result may be eligible to receive targeted treatment with PBS-subsidised futibatinib in 2L+. This change is expected to lead to a significant improvement in clinical outcomes, as demonstrated by the pivotal FOENIX-CCA2 study.

Proposed MBS items

Proposed Item AAAAA

MBS item number:

Please search and select the proposed category:

Category 6 - Pathology Services

Please search and select the proposed group:

P7 - 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 FGFR2 fusion or rearrangement in tumour tissue from a patient with histologically confirmed locally advanced or metastatic cholangiocarcinoma, if: the test is requested by a specialist or consultant physician to determine if requirements relating to FGFR2 fusion or rearrangement status for access to futibatinib under the Pharmaceutical Benefits Scheme are fulfilled.

Proposed MBS fee:

\$0.00

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:

MBS fee to be confirmed, noting that the fee for item 73433 (NGS test for NTRK fusions) is \$1000.00.
Overall cost to be confirmed in the integrated codependent submission

Proposed Item BBBB

MBS item number:

Please search and select the proposed category:

Category 6 - Pathology Services

Please search and select the proposed group:

P7 - 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:

Fluorescence in-situ hybridisation (FISH) test of tumour tissue from a patient with histologically confirmed locally advanced or metastatic cholangiocarcinoma, if:
the test is requested by a specialist or consultant physician to determine if requirements relating to FGFR2 fusion or rearrangement status for access to futibatinib under the Pharmaceutical Benefits Scheme are fulfilled.

Proposed MBS fee:

\$0.00

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:

MBS fee to be confirmed, noting that the fee for item 73430 (FISH test for NTRK fusions) is \$400.00.
Overall cost to be confirmed in the integrated codependent submission.

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

Any testing 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:

Based on the results of FOENIX-CCA2, testing to detect FGFR2 fusion or rearrangement, followed by targeted therapy with futibatinib results in superior health outcomes compared to no testing and untargeted treatment/best supportive care in patients with locally advanced or metastatic CCA. In FOENIX-CCA2, 42% of the patients who received futibatinib had a response, as determined by independent central review. The use of futibatinib resulted in durable responses and survival that surpassed those indicated by historical data with chemotherapy in patients with refractory CCA.

Estimated utilisation

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

The incidence of CCA in Australasia has been reported as 0.3 to 3.5 cases per 100,000 population and it is understood that CCA affects approximately 1,300 Australians each year. Patients with CCA commonly present with advanced disease; at diagnosis, ~60-70% of patients have unresectable disease.

The prevalence and/or incidence of the proposed population will be estimated in the codependent submission.

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

Year 1 estimated uptake(%):

0

Year 2 estimated uptake(%):

0

Year 3 estimated uptake(%):

0

Year 3 estimated uptake(%):

0

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

To be determined and presented in the codependent submission for both test and treatment.

Optionally, provide details:

Uptake has been set to zero as a means to submit this application form. Utilisation estimates, including uptake % and number of patients utilising, will be presented in detail in the codependent submission for the the test and treatment.

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 Pathologists of Australia (RCPA)

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

Professional body name:

Clinical Oncology Society of Australia (COSA)

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:

COSA

Professional body name:

MOGA

Professional body name:

RCPA

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

Number of organisations listed: 1

Professional body name:

Rare Cancers Australia (RCA)

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

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:

This application requests Medicare Benefits Schedule (MBS) listing for testing to detect FGFR2 fusions or rearrangements in patients with locally advanced or metastatic cholangiocarcinoma (CCA), to determine Pharmaceutical Benefits Scheme (PBS) eligibility for futibatinib (Lytgobi), a potent and highly selective kinase inhibitor of fibroblast growth factor receptor (FGFR) 1-4, for patients who have locally advanced or metastatic CCA and who have progressed following at least one prior line of systemic therapy. The PBS restriction for futibatinib will require patients to have confirmed FGFR2 fusion or rearrangement.