

MSAC application 1792

Immunohistochemistry testing for FGFR2b expression in patients with unresectable locally advanced or metastatic gastric or gastro-oesophageal cancer, to determine eligibility for PBS subsidised bemarituzumab treatment

Application for MBS eligible service or health technology

HPP Application number:

HPP200225

Application title:

Immunohistochemistry testing for FGFR2b expression in patients with unresectable locally advanced or metastatic gastric or gastro-oesophageal cancer, to determine eligibility for PBS subsidised beemarituzumab treatment

Submitting organisation:

AMGEN AUSTRALIA PTY LIMITED

Submitting organisation ABN:

31051057428

Application description

Succinct description of the medical condition/s:

Unresectable locally advanced or metastatic gastric or gastro-oesophageal junction cancer that is human epidermal growth factor receptor 2 (HER2) negative and positive for fibroblast growth factor receptor 2b (FGFR2b) overexpression.

Succinct description of the service or health technology:

The submission requests the MBS listing of immunohistochemistry (IHC) testing for the measuring of fibroblast growth factor receptor 2b (FGFR2b) expression in gastric or gastro-oesophageal junction cancer tumours, to determine eligibility for treatment with beemarituzumab under the PBS.

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

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

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:

Histopathology and cytology

PICO sets

Application PICO set:

FGFR2b IHC testing in gastric or gastro-oesophageal junction cancer

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

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:

Adult patients (≥ 18 years of age) with unresectable locally advanced or metastatic gastric or gastro-oesophageal junction adenocarcinoma

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

Late gastric cancer

Intervention

Name of the proposed health technology:

Immunohistochemistry testing for FGFR2b expression - VENTANA FGFR2b (FPR2-D) RxDx 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:

Comparator: No FGFR2b expression testing.

In current practice, treatment allocation in unresectable locally advanced or metastatic gastric or gastro-oesophageal cancer (G/GOJC) is based on HER2 testing, with HER2+ patients receiving chemotherapy +/- trastuzumab and HER2- patients receiving chemotherapy +/- nivolumab. HER2 testing is conducted via an immunohistochemistry (IHC) test and/or an in situ hybridisation (ISH) test. Tumour samples taken from biopsies, initially used for confirming G/GOJC diagnoses, are subsequently used for HER2 biomarker testing.

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 outcome of FGFR2b testing will impact the management of patients with unresectable locally advanced or metastatic G/GOJC, as FGFR2b overexpression is predictive of response/benefit to bemarituzumab treatment. Under the proposed PBS listing, patients positive for FGFR2b overexpression (FGFR2b+) will be eligible for BEMA+CTX or NIVO+CTX, whereas those negative for FGFR2b overexpression (FGFR2b-) will continue to receive NIVO+CTX. The proposed threshold for a positive result for FGFR2b overexpression is an IHC staining score of 2+ (moderate to strong) or 3+ (strong) in $\geq 10\%$ tumour cells.

Use of BEMA+CTX in FGFR2b+ patients is expected to improve patient prognosis compared to NIVO+CTX, via improved survival outcomes (PFS and OS), and will impact health harms experienced by patients as a result of differences in their respective safety profiles.

Proposed MBS items

Proposed item:

AAAAA

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

Category number:

PATHOLOGY SERVICES

Category description:

TISSUE PATHOLOGY

Proposed item descriptor:

Immunohistochemical examination of tumour tissue from a patient with locally advanced unresectable or metastatic gastric/gastro-oesophageal junction adenocarcinoma to determine eligibility relating to fibroblast growth factor receptor 2b (FGFR2b) expression for access to treatment with bemarituzumab under the Pharmaceutical Benefits Scheme (PBS).

Proposed MBS fee:

\$125.00

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

\$125.00

Please specify any anticipated out of pocket expenses:

\$0.00

Provide any further details and explain:

No out of pocket costs are expected as the proposed fee is sufficient to cover the cost of the service.

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

FGFR2b testing is not currently funded in Australia

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:

FGFR2b testing alone will have no impact on health outcomes. However, in combination with bemarituzumab treatment in FGFR2b+ patients, these co-dependent technologies are expected to impact health outcomes in patients with HER2- unresectable locally advanced or metastatic G/GOJC.

In the forthcoming co-dependent (MSAC/PBAC) submission, clinical claims will be based on the indirect comparison of the active Phase 3 FORTITUTE-101 trial (BEMA+CTX vs PBO+CTX) and the Checkmate 649 trial (NIVO+CTX vs PBO+CTX). These clinicals claims are expected to be superior effectiveness and non-inferior safety for the co-dependent technologies of FGFR2b testing and treatment with bemarituzumab (plus chemotherapy) relative to no FGFR2b testing and treatment with nivolumab (plus chemotherapy).

The expectation of superior effectiveness for BEMA+CTX versus NIVO+CTX is based on the naïve indirect comparison of outcomes from the FIGHT trial and the Checkmate 649 trial, with a 57% reduction in PFS and 48% reduction in OS observed for BEM+CTX vs CTX alone in the 'Tumor IHC Staining Score of 2+ or 3+ in ≥10% of

Cells' subgroup of FIGHT, compared to a 21% reduction in both PFS and OS for NIVO+CTX versus CTX alone in the 'ITT' cohort of Checkmate 649.

Estimated utilisation

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

The incidence of gastric cancer in Australia increased from 2,248 new cases in 2015 to 2,584 new cases in 2024 (AIHW 2024). Based on the extrapolation of these data, it is estimated that 2,669 new cases of gastric cancer will be diagnosed in 2026. The PBAC previously accepted financial estimates for nivolumab in gastric cancer that assumed 84.1% of gastric cancer patients will have adenocarcinoma histology and 75% will be diagnosed with unresectable advanced or metastatic disease (November 2021 nivolumab PSD, Table 14). Based on these assumptions, it is estimated there will be 1,649 incident patients with unresectable advanced or metastatic gastric adenocarcinoma in 2025.

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:

1669

Optionally, provide details:

The estimation of 100% uptake of FGFR2b testing among eligible patients is based on an assumption of superior effectiveness for bemarituzumab (plus chemotherapy) compared to nivolumab (plus chemotherapy) in HER2-/FGFR2b+ patients. Should superior effectiveness be established in the forthcoming co-dependent submission,

then all eligible patients are expected to uptake FGFR2b testing to ensure access to beemarituzumab under the PBS for patients who are HER2- and FGFR2b+. Estimated uptake also reflects the proposed positioning of FGFR2b testing parallel to HER2 testing in G/GOJC.

Uptake of beemarituzumab will be estimated in the codependent submission.

Will the technology be needed more than once per patient?

No, once only

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 requests the health technology/service

Medical Oncology Group of Australia

Private Cancer Physicians of Australia Limited

Clinical Oncology Society of Australia Limited

Gastroenterological Society of Australia

Entity who may be impacted by the health technology/service

Medical Oncology Group of Australia

Private Cancer Physicians of Australia Limited

Gastroenterological Society of Australia

Australasian Gastro-Intestinal Trials Group

Clinical Oncology Society of Australia Limited

Entity who provides the health technology/service

Royal College of Pathologists of Australasia

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

PANCARE Foundation

GI Cancer Institute

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 intended purpose in this application the same as the intended purpose of the ARTG listing(s)?

Yes

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)?

Yes

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 MBS funding for the testing of fibroblast growth factor receptor 2b (FGFR2b) expression in patients with unresectable locally advanced or metastatic gastric or gastro-oesophageal junction cancer (G/GOJC), to determine PBS eligibility for bemarituzumab. The PBS restriction for bemarituzumab will specify use in patients who test positive for FGFR2b overexpression.