Medical Services Advisory Committee (MSAC) Public Summary Document

Application No. 1779.1 – Testing of tumour tissue to detect FGFR2 fusions or rearrangements in people with cholangiocarcinoma, to determine eligibility for treatment with PBS subsidised futibatinib

Applicant: **Taiho Pharma Oceania Pty Ltd.**

Date of MSAC consideration: **27 November 2025**

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, visit the MSAC website

1. Purpose of application

This codependent application requests:

- Medicare Benefits Schedule (MBS) listing of testing of tumour tissue to detect fibroblast growth factor receptor 2 (*FGFR2*) fusions or rearrangements; and
- Pharmaceutical Benefits Scheme (PBS) Authority required (streamlined) listing of futibatinib for the treatment of locally advanced or metastatic cholangiocarcinoma (CCA) in patients with *FGFR2* fusion or rearrangement.

This streamlined resubmission aimed to address the key issues identified by MSAC at its July 2025 meeting. A separate PBAC resubmission was considered by PBAC at its November 2025 meeting.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost, MSAC supported the creation of a new Medicare Benefits Schedule (MBS) item for testing of tumour tissue to detect *FGFR2* fusions or rearrangements in people with cholangiocarcinoma (CCA), to determine eligibility for treatment with Pharmaceutical Benefits Scheme (PBS) subsidised futibatinib. MSAC noted that at its November 2025 meeting the Pharmaceutical Benefits Advisory Committee was of a mind to recommend PBS listing of futibatinib, pending MSAC support for the MBS listing of the associated test. MSAC considered that the MBS item should be a gene panel test and include at least the detection of alterations in both *FGFR2* and *IDH1* genes (the latter is already listed on the MBS; item 73319).

MSAC acknowledged that there is a high clinical need for effective treatments in patients with CCA. MSAC considered a combined next generation sequencing (NGS) test on DNA and RNA as the most appropriate method to ensure that *FGFR2* fusions and rearrangements are accurately detected. At its April 2025 meeting, MSAC considered that DNA and RNA NGS testing was safe and effective. Given the rapid and aggressive nature of the disease, MSAC considered that *FGFR2* testing should occur at the time of CCA diagnosis to prevent any delays in treatment decisions. MSAC considered an MBS fee of $800 appropriate for this DNA and RNA NGS gene panel test. MSAC considered that the cost to the MBS of testing at CCA diagnosis was acceptable. MSAC considered that there is a

risk that testing may occur outside of the intended CCA population and advised reviewing the utilisation of the new MBS item 2 years after its implementation.

MSAC confirmed the following MBS item descriptor:

Category 6 – Pathology Services	
Proposed item descriptor XXXXX	Group P7 - Genetics
A nucleic acid-based multi-gene panel test of tumour tissue from a patient with cholangiocarcinoma requested by, or on behalf of, a specialist or consultant physician, if the test is: (a) To detect at least *IDH1* variant status, and (b) To detect the fusion or rearrangement status of at least *FGFR2,* and (c) To determine eligibility for a relevant treatment under the Pharmaceutical Benefits Scheme (PBS), and including (if performed) a service described in item 73319 Applicable only once per lifetime.	
Fee: $800 Benefit: 75% = $600 85% = $695.50	

The 85% benefit reflects the 1 November 2025 Greatest Permissible Gap (GPG) of $104.50. All out-of-hospital Medicare services that have an MBS fee of $697.00 or more will attract a benefit that is greater than 85% of the MBS fee – being the schedule fee less the GPG amount. The GPG amount is indexed annually on 1 November in line with the Consumer Price Index (CPI) (June quarter).

Consumer summary

This application from Taiho Pharma Oceania Pty Ltd was submitted to both the Pharmaceutical Benefits Advisory Committee (PBAC) and Medical Services Advisory Committee (MSAC). It is the third time the application has been considered by both committees. The application is requesting Medicare Benefits Schedule (MBS) listing of a tumour tissue test to detect fibroblast growth factor receptor 2 (*FGFR2*) gene variants in patients with cholangiocarcinoma (CCA). This application is a 'codependent' application which means in order for a recommendation of public funding, PBAC would need to recommend PBS listing of futibatinib and MSAC would have to recommend public funding for the test. The resubmission proposed that people whose tumours have *FGFR2* variants would be eligible to access a medicine called futibatinib. As a part of the co-dependent application, the applicant has also requested listing of futibatinib on the Pharmaceutical Benefits Scheme (PBS). Applications for new medicines to be listed on the PBS are considered by the PBAC.

At its November 2025 meeting, the PBAC agreed to recommend PBS listing of futibatinib, if MSAC supported the MBS listing of the test. The MSAC had previously considered this application at its April and July 2025 meetings. MSAC acknowledged that *FGFR2* testing is safe, effective and that the link between *FGFR2* testing and effective treatment with futibatinib (codependency) has been established. However, MSAC did not support the listing of *FGFR2* testing at its previous consideration due to unresolved issues in the application regarding the testing population, economic and financial analyses.

CCA is also known as bile duct cancer. The bile ducts are a group of thin tubes starting inside the liver that carry bile from the liver and gallbladder into the small intestine. CCA is a rare and aggressive form of cancer, with not many treatment options available. Because of this, survival after diagnosis is usually relatively short, with only half of the people alive a year after diagnosis. Therefore, there is a need for people to have access to more effective treatments.

This genetic testing targets the *FGFR2* gene. The FGFR2 protein is associated with cell growth and differentiation, and is implicated in cancer growth. *FGFR2* variants are mainly found in CCA and not in other cancers. Given the aggressiveness of CCA, MSAC considered that *FGFR2* testing should be done at the time of CCA diagnosis. CCA can get worse very quickly and testing at diagnosis would reduce treatment delays. In the current resubmission, the applicant

Consumer summary
had revised the economic and financial analyses to include the whole CCA population at diagnosis. MSAC considered this acceptable. MSAC considered that the most appropriate way to accurately detect *FGFR2* variants is a test performed on both DNA and RNA, which is called a combined DNA and RNA next generation sequencing (NGS) test. MSAC noted that there are other genes in CCA that can be tested at the same time as *FGFR2* testing. This includes the *IDH1* gene which already has an MBS item. MSAC considered that the methods used to test for *FGFR2* variants should also test for other genes at the same time. Therefore, MSAC considered that the MBS item should be for a test for multiple genes, which is called a gene panel test. MSAC advised that the fee for this test should be the same as the fee for a gene panel test already listed on the MBS (item 73376). MSAC was concerned about potential out-of-pocket costs. MSAC advised the Department to monitor out-of-pocket costs to patients due to this testing. CCA can be hard to diagnose as it can look similar to other cancers when examined under the microscope. MSAC considered that there is possibility that other cancers which are located close to the bile ducts may be thought to be CCA when in fact they are not. Therefore, MSAC considered that this may increase the number of *FGFR2* testing more than expected. For this reason, MSAC requested a review of the item's usage be conducted 2 years after its listing on the MBS. MSAC considered its previous concerns regarding the testing population, the economic and financial analyses had been adequately addressed. MSAC considered that the test was safe, effective and good value for money. **MSAC's advice to the Commonwealth Minister for Health, Disability and Ageing** MSAC supported MBS listing of a tumour tissue test using a gene panel to detect *FGFR2* gene variants in patients with CCA. MSAC acknowledged that *FGFR2* testing is safe, effective and considered that *FGFR2* testing is needed so patients can be treated with futibatinib on the PBS. MSAC considered that the test was good value for money and had an acceptable financial impact on the MBS if testing is performed in the intended CCA population. MSAC advised that a review of the usage of *FGFR2* testing should be performed 2 years after it is MBS listed.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted that this was a codependent resubmission from Taiho Pharma Oceania Pty Ltd for Medicare Benefits Schedule (MBS) listing of testing of tumour tissue to detect fibroblast growth factor receptor 2 (*FGFR2*) fusions or rearrangements in people with cholangiocarcinoma (CCA), to determine eligibility for treatment with Pharmaceutical Benefits Scheme (PBS) subsidised futibatinib.

MSAC acknowledged that patients with CCA typically have a poor prognosis, and that there is a high clinical need for new treatment options for this patient population. MSAC noted that at its November 2025 meeting the Pharmaceutical Benefits Advisory Committee was of a mind to recommend PBS listing of futibatinib, pending MSAC support for the MBS listing of the associated test. MSAC recalled it had previously considered this submission at its April 2025 meeting (where it deferred providing advice) and its July 2025 meeting (where it did not support listing of the test). At its April 2025 consideration, MSAC considered that *FGFR2* testing was safe, effective and that the claim of codependency of *FGFR2* testing and futibatinib was reasonable based on the available (albeit limited) information. At its July 2025 meeting, MSAC's key matters of

concern related to the appropriate testing population, test fee and the impacts of testing on the economic and financial analyses.

MSAC reaffirmed its previous advice that *FGFR2* testing should be performed at the time of CCA diagnosis, given the rapidly progressive nature of the disease. Testing at diagnosis helps avoid delays and ensures timely access to treatment if the disease progresses to an advanced or metastatic stage. MSAC noted that the current resubmission had increased the testing population three-fold compared to the initial submission to account for testing of the entire CCA population at diagnosis. MSAC considered that this was acceptable. MSAC recalled its previous concern that testing may be expanded to populations outside of the intended CCA population (e.g. patients with pancreatic cancer or cancer of unknown primary [CUP]) due to diagnostic uncertainty. MSAC noted that the resubmission had increased the size of the testing population by 1% to account for this. While MSAC acknowledged that there is significant uncertainty in the proportion of patients outside of the intended CCA population who may access the testing in practice, MSAC considered that this population is likely to be higher than 1% as assumed in the resubmission.

MSAC noted the proposed MBS item descriptors. MSAC recalled its previous advice that a combined next generation sequencing (NGS) test on DNA and RNA as the most appropriate method to ensure that *FGFR2* fusions and rearrangements are accurately detected. MSAC also recalled its advice that single gene testing of tumour tissue may no longer be efficient or cost-effective for pathology laboratories and that laboratories would likely include both *IDH1* sequencing (currently listed on the MBS for testing in the CCA population: MBS item 73319) and *FGFR2* testing on a gene panel. Therefore, MSAC considered it appropriate for *FGFR2* testing to be on a gene panel (with *IDH1*), rather than as a single gene test. Given the presence of other therapeutically relevant gene variants in CCA[1], MSAC considered that an NGS gene panel test would future-proof the MBS item by enabling additional genes to be included as new evidence and targeted treatments emerge. MSAC advised that the testing should be pathologist determinable, which is in alignment with the current *IDH1* testing MBS item (item 73319).

Regarding the test fee, MSAC recalled it had requested an appropriate fee for a gene panel test including *FGFR2* and *IDH1* to be used for the economic and financial analyses. MSAC noted that the current resubmission proposed a fee of $885 and noted that this was the private cost of an NGS DNA and RNA panel test at Peter MacCallum Cancer Centre. However, MSAC considered that it was appropriate to align the fee with an already available MBS item for a gene panel test (item 73376) and therefore considered that a fee of $800 was appropriate. MSAC was concerned about out-of-pocket costs that may be faced by patients accessing this test and requested for this to be reviewed post implementation.

MSAC noted the economic and financial analyses presented in the resubmission, and the additional analyses conducted by the department. MSAC recalled that the previous submissions inappropriately assumed that 20-40% of testing would be performed at no cost, as this is currently provided by Omico in clinical practice. However, MSAC considered it unlikely that Omico would continue to perform this testing at no cost if the testing was listed on the MBS. MSAC noted that the current resubmission has removed the assumption that any testing would be performed at no cost, which MSAC considered to be appropriate.

[1] Kendre G, Murugesan K, Brummer T, Segatto O, Saborowski A, Vogel A. Charting co-mutation patterns associated with actionable drivers in intrahepatic cholangiocarcinoma. *J Hepatol*. 2023;78(3):614-626. doi:10.1016/j.jhep.2022.11.030

MSAC noted the resubmission provided an updated economic model which included a gene panel test fee of $885 ($545 applied in the model after removing $340 for *IDH1* testing)[2], removing the assumption that any testing would occur at no cost, increasing the test population by three fold from the initial submission to account for testing at CCA diagnosis, and increasing the testing population by an additional 1% to account for testing in patients outside of the intended CCA population. MSAC noted that this led to the resubmission's base case incremental cost-effectiveness ratio (ICER) of $75,000 to < $95,000. MSAC noted that the department had conducted additional analysis which found that the resubmission's base case ICER may be an over-estimate due to an underestimate of the diagnostic yield of the test used within the modelling. MSAC agreed with the department that the base case ICER should only include testing within the intended CCA population and that a sensitivity analysis would more appropriately address testing outside this population. Revised analysis by the department, which included testing only in patients with CCA, an adjusted diagnostic yield to 10.1%[3], and a gene panel test fee of $800 ($460 applied in the model after removing $340 for *IDH1* testing)[2] resulted in a revised ICER of $55,000 to < $75,000. MSAC considered this to be a more accurate estimate of the base case ICER and considered the result to be acceptable.

MSAC noted the financial analysis presented in the resubmission. MSAC noted that the department revised financial impact, which included the revised diagnostic yield of 10.1% and a test fee of $800, was estimated as $0 to < $10 million in year 1 rising to $0 to < $10 million in year 6. MSAC considered that this was a reasonable estimate. MSAC also noted the departments sensitivity analysis which indicated that if 25% of patients with pancreatic cancer or CUP were assumed to access the test in addition to the intended CCA population, the financial impact to the MBS would increase to approximately $0 to < $10 million in year 1 and $0 to < $10 million in year 6. MSAC considered that a test uptake of 25% by patients with pancreatic cancer or CUP represent a scenario of significant test use outside the intended CCA population. Given the significant uncertainty in the proportion of patients outside of the intended CCA population that might access the test, MSAC advised for a post-implementation utilisation review to be conducted at 2 years.

Overall, considering the department revised economic and financial analyses, MSAC supported public funding of testing of tumour tissue to detect *FGFR2* fusions or rearrangements in people with CCA, to determine eligibility for treatment with PBS subsidised futibatinib.

4. Background

On two prior occasions (April and July 2025) MSAC considered testing of tumour tissue to detect *FGFR2* fusions or rearrangements in people with CCA, to determine eligibility for treatment with PBS subsidised futibatinib (MSAC 1779).

At its July 2025 consideration, MSAC did not support the proposed test. MSAC advised revising the economic and financial analyses by including an updated test fee, testing the whole CCA population at diagnosis, removing the assumption that 20% of testing will be performed at no cost by Omico and accounting for testing conducted outside of the intended CCA population. MSAC also considered that further advice from the Department of Health, Disability and Ageing (the department) was required on the appropriate MBS fee for panel testing. MSAC reiterated

[2] At its July 2025 meeting, MSAC considered it was reasonable to only account for the incremental difference between the single gene *IDH1* test fee and the proposed gene panel fee in the economic and financial analyses.

[3] The initial submission presented several studies that reported prevalence of *FGFR2* fusions and rearrangements in the whole CCA population. The reported prevalence ranged from 3.2% to 16.9%. The 10.1% diagnostic yield used in the department revised analyses was calculated by combining results from all the studies (1,016 out of 10,041 cases).

that the claim of codependency of *FGFR2* testing and futibatinib was reasonable. MSAC considered that the outstanding issues relating to the testing component could be addressed as a streamlined application.

A summary of key matters of MSAC concern from the July 2025 consideration (page 5 from the MSAC 1779 July 2025 PSD) and how the MSAC 1779.1 resubmission addresses these concerns is provided in Table 1.

Table 1: Summary of key matters of MSAC concern

Component	Matter of concern	How the current assessment report addresses it
Test fee	An appropriate fee for a gene panel test including *FGFR2* to be used for economic and financial analysis. MSAC requested further advice from the department on this matter.	The MSAC 1779.1 resubmission has proposed a fee of $885 noting that this is the private cost of an NGS DNA and RNA panel test at Peter MacCallum Cancer Centre.
Testing population	MSAC considered that *FGFR2* testing should occur in the whole CCA population at diagnosis to prevent any delays in treatment decisions as it is a rapidly progressing cancer and the tumour samples for testing are small.	The MSAC 1779.1 resubmission has increased the test population by 357% compared to the initial submission to account for testing at CCA diagnosis.
Testing population	Address the issue of expansion of the testing to populations outside of the intended CCA population (e.g. pancreatic cancer and cancer of unknown primary [CUP]).	The 1779.1 resubmission has increased the testing population by 1% to account for testing in populations outside of the intended CCA population.
Financial impact of testing	Revise the economic and financial analyses by removing the assumption that 20% of the testing will be performed at no cost	Addressed – free of charge testing by Omico set to 0%.

Abbreviations: CCA = cholangiocarcinoma; DNA = deoxyribonucleic acid; *FGFR2* = fibroblast growth factor receptor 2; MSAC = Medical Services Advisory Committee; NGS = next generation sequencing; RNA = ribonucleic acid

The PBAC considered listing of futibatinib for the treatment of patients with locally advanced or metastatic CCA who have previously progressed on systemic therapy and have a *FGFR2* fusion or rearrangement at its March and July 2025 meetings. At its March 2025 meeting, the PBAC did not recommend PBS listing of futibatinib and advised that a resubmission should include a more realistic estimate of the clinical benefit in the economic model and revise utilisation estimates to more accurately reflect the prevalence of CCA and the number of patients with *FGFR2* fusions or rearrangements. PBAC considered the resubmission at its July 2025 meeting, where it again did not recommend PBS funding of futibatinib as the resubmission did not adequately address the outstanding issues requested as part of its March 2025 consideration. A resubmission addressing the outstanding issues will be considered again by PBAC at its November 2025 meeting.

MSAC application 1750: Testing of tumour tissue to detect isocitrate dehydrogenase 1 [*IDH1*] mutations in patients with CCA to determine eligibility for ivosidenib on the PBS was supported by MSAC at its November 2024 meeting. PBAC recommended ivosidenib for treatment of locally advanced or metastatic CCA with an *IDH1* mutation in patients who have previously progressed

on chemotherapy at it November 2024 meeting. Ivosidenib was listed on the PBS and *IDH1* testing listed on the MBS (Item 73319) on 1 July 2025.[4,5]

5. Prerequisites to implementation of any funding advice

LYTGOBI (futibatinib) has been granted provisional registration by the TGA in the Australian Register of Therapeutic Goods (ARTG). The indication is:

'LYTGOBI monotherapy has provisional approval in Australia for the treatment of adult patients with locally advanced or metastatic intrahepatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy. The decision to approve this indication has been made on the basis of the favourable objective response rate and duration of response in a single arm trial. Continued approval of this indication depends on verification and description of benefit in confirmatory trials.'

At its March 2025 meeting the PBAC considered it would be appropriate for futibatinib to be listed for patients with locally advanced or metastatic CCA who have previously progressed on systemic therapy and who have evidence of an *FGRF2* fusion or rearrangement. The PBAC agreed with the ESCs that it can be difficult to differentiate between intrahepatic and extrahepatic CCA and it was likely futibatinib would provide benefit in the small population of patients with non-intrahepatic CCA who have an *FGFR2* fusion or rearrangement.

The MSAC 1779.1 resubmission considered that *FGFR2* fusions or rearrangements testing is expected to be conducted in specialist laboratories who hold the appropriate accreditation and registration for this testing procedure to receive MBS funding. Laboratories will need to participate in the relevant Royal College of Pathologist of Australasia (RCPA) Quality Assurance Program. Testing must be conducted, and the results interpreted and reported by suitably qualified and trained molecular pathologists.

Through correspondence with the department, the applicant confirmed that many laboratories in Australia currently offer National Association of Testing Authorities (NATA) accredited testing for *FGFR2* fusions, supported by an established external quality assessment program.

6. Proposal for public funding

A new MBS listing is being requested for testing of tumour tissue to detect *FGFR2* fusions or rearrangements in people with CCA, to determine eligibility for treatment with PBS subsidised futibatinib.

In the initial submission, the ESCs proposed the following MBS item descriptor if a single gene test for *FGFR2* is supported.

[4] Medicine Status Website, Ivosidenib, accessed 9 October 2025

[5] MBS Online Medicare Benefits Schedule, Item 73319, accessed 24 October 2025

Category 6 – Pathology Services	
Proposed item descriptor XXXXX	Group P7 - Genetics
A nucleic acid-based test of tumour tissue for FGFR2 fusions or rearrangements in a patient with cholangiocarcinoma requested by, or on behalf of, a specialist or consultant physician to determine access to a relevant treatment under the Pharmaceutical Benefits Scheme (PBS) Applicable only once per lifetime.	
Fee: $682.35 Benefit: 75% = $511.80 85% = $580.00	

In the consideration of the initial submission, MSAC considered that a single MBS item for a DNA and RNA NGS panel test for *FGFR2* fusions and rearrangements and *IDH1* sequencing (Application 1750 supported by MSAC in November 2024 for the whole CCA population) would be appropriate if both tests are funded. The ESCs proposed the following MBS item descriptor if panel testing is supported.

Category 6 – Pathology Services	
Proposed item descriptor XXXXX	Group P7 - Genetics
A nucleic acid-based multi-gene panel test of tumour tissue from a patient with cholangiocarcinoma requested by, or on behalf of, a specialist or consultant physician, if the test is: (a) To detect at least IDH1 variant status, and (b) To detect the fusion or rearrangement status of at least FGFR2 (c) To determine access to a relevant treatment under the Pharmaceutical Benefits Scheme (PBS) Applicable only once per lifetime.	
Fee: $TBC Benefit: 75% = $TBC 85% = $TBC	

TBC: to be confirmed

7. Population

Testing in locally advanced or metastatic disease

In its previous considerations, MSAC recommended that all patients undergo *FGFR2* testing at the time of CCA diagnosis.

The MSAC 1779.1 resubmission noted that the test population was increased by 200% in the July 2025 PBAC resubmission to account for testing earlier in the algorithm (i.e. all patients who receive first line treatment in the locally advanced or metastatic disease stages receive testing). The MSAC 1779.1 resubmission noted that including locally advanced or metastatic patients who elect no first-line treatment resulted in a 286% increase in testing, and including all patients at the first diagnosis of CCA as proposed by MSAC (i.e. either early stage or advanced disease) would result in a 357% increase in testing. The MSAC 1779.1 resubmission has updated the economic and financial analyses by increasing the test population by 357% (compared to the initial submission) to account for testing at CCA diagnosis.

The MSAC 1779.1 resubmission considered that testing at the point of CCA diagnosis will result in additional cost to the MBS, much of which will be attributable to testing in patients who will never be assessed for eligibility for treatment in the second line advanced setting (futibatinib and/or ivosidenib), including those who elect no treatment at all in the advanced disease setting.

Testing of patients with pancreatic cancer and cancer of unknown origin

In its previous considerations, MSAC considered there is a risk that *FGFR2* testing may be used outside of the intended CCA population for other cancers as it can be difficult to differentiate CCA and other cancer in nearby organs (e.g. pancreatic cancers and CUP). MSAC requested the applicant to present revised economic and financial analyses taking into account the testing that may be performed in (unintended) non-CCA populations in practice.

The MSAC 1779.1 resubmission updated the economic and financial analyses to account for potential misdiagnoses by increasing the testing population by 1%. The MSAC 1779.1 noted that no evidence regarding the proportion of misdiagnoses in CCA was identified.

The department conducted consultation with The Royal College of Pathologists of Australasia (RCPA) and Public Pathology Australia (PPA) as a part of the previous submission. As part of this consultation, RCPA and PPA were asked to advise on an estimate of the proportion and number of patients with pancreatic cancers and CUP who may be suspected of having CCA and tested for *FGFR2* fusions or rearrangements.

The RCPA stated that there is significant uncertainty, but the number is likely very small especially after multidisciplinary team (MDT) review. They suggested that requiring a final MDT diagnosis of CCA could help reduce uncertainty and recommended using World Health Organization terminology of “intrahepatic cholangiocarcinoma” and “carcinoma of the extrahepatic bile ducts” to clearly distinguish between intrahepatic and extrahepatic CCA. RCPA noted that the clinical trials that supported funding for *FGFR2* testing likely included a small proportion of patients who may not have had true CCA, and this uncertainty may already be reflected in the clinical and cost-effectiveness estimates.

PPA provided an estimate for South Australia, noting around 100 cases of CCA are diagnosed annually, with approximately 200 cases entering the differential diagnosis between CCA and pancreatic cancer. They noted that SA Pathology captures about 60% of these cases, therefore they estimate around 200 patients would be tested for *FGFR2* fusions on the MBS each year.

8. Comparator

No change to the drug or test comparator compared with the previous submission.

9. Summary of public consultation input

No further public consultation input was received.

10. Characteristics of the evidence base

No change to the evidence base for the test component compared with the previous submission.

11. Comparative safety

No change to claim of comparative safety for the drug or test component compared with the previous submission.

12. Comparative effectiveness

The current resubmission to PBAC altered the overall survival hazard ratio (to 0.48 from 0.24) based on the PBAC recommendation from the July 2025 meeting. This increased the overall survival associated with FOLFOX treatment, reduced incremental QALYs and increased the ICER. No change occurred to the futibatinib PFS or OS curves.

13. Economic evaluation

The applicant had changed three key inputs in their PBAC resubmission to be considered at the November 2025 PBAC meeting:

- The change in the overall survival hazard ratio (HR) to 0.48 was accompanied by a structural change to permit use of HRs in the model.
- The time horizon was reduced from 10 to 5 years.
- The effective approved ex-manufacturer price (AEMP) of futibatinib was reduced from $**Redacted** per pack to $**Redacted**

These input changes resulted in an ICER of $55,000 to < $75,000/QALY in the resubmission to PBAC per identified patient treated with futibatinib. The economic analysis in the resubmission to be considered by PBAC in November 2025 assumed the following: a fee of $350 to test *FGFR2*, 40% of the testing conducted at no cost by Omico, *FGFR2* variant prevalence of 20% with no additional testing (compared to the previous submission) to capture testing at CCA diagnosis and testing in unintended populations (i.e. in patients with CUP or pancreatic cancer).

At the July 2025 meeting, the MSAC proposed the following three changes to the test component (page 5 ratified minutes):

1. Include testing costs for all patients diagnosed with CCA at the point of diagnosis for all economic modelling and financial impact analysis.
2. Address the issue of expansion of the testing to populations outside of the intended CCA population (e.g. pancreatic cancer and CUP).
3. Revise the economic and financial analyses by removing the assumption that 20% of the testing will be performed at no cost.

This resubmission has made the following changes to address MSAC's concerns:

1. Increase in testing population to include testing at CCA diagnosis (i.e. 357% additional testing versus initial submission).
2. Increased the testing population by 1% to include testing in patients with pancreatic cancer and CUP.
3. Removed the assumption that 20% of the testing will be performed at no cost by Omico.

At the July 2025 meeting MSAC also requested further advice from the department on the appropriate MBS fee for gene panel testing. The MSAC 1779.1 resubmission has assumed a test fee of $885. This is the same fee used by the applicant in the previous submission, which noted

that the private cost of an NGS DNA and RNA panel test at Peter MacCallum Cancer Centre is $885.[6]

In the economic and financial analyses of the current resubmission, a test fee of $545 has been used as this is the incremental difference between the single gene *IDH1* test fee ($340, MBS item 73319) and the applicant proposed gene panel fee ($885). This approach (i.e. using the incremental fee difference) was considered to be reasonable by MSAC at its July 2025 meeting.

The MSAC 1779.1 resubmission noted that applying testing inputs advised by MSAC resulted in a test cost of $14,137.46 to identify one patient treated with futibatinib and costing for the test represented Redacted% of the overall incremental cost. The MSAC 1779.1 resubmission considered that the test component may be disproportionate to the overall cost of this codependent technology and noted that this should be considered in the context of the rare and aggressive nature of this cancer.

Table 2 presents the results of the economic evaluation presented in the MSAC 1779.1 resubmission using the values described above.

Table 2: Cost results from the economic model

		Disaggregated costs						
	Total costs ($)	**PF**	**PD**	**AE**	**EOL**	**Drug acquisition**	**Drug admin.**	**Test costs**
Futibatinib	$**Redacted**	$2,214	$954	$802	$42,393	$**Redacted**	$0	$14,137
Chemotherapy	$59,916	$1,988	$600	$1,577	$48,611	$3,102	$4,038	$0
Incremental cost	$**Redacted**	$226	$354	-$774	-$6,218	$**Redacted**	-$4,038	$14,137
% of incremental cost		**Redacted** %	**Redacted** %	**-Redacted** %	**-Redacted** %	**Redacted** %	**-Redacted** %	**Redacted** %

Abbreviations: AE = adverse events, EOL = end of life costs, PD = progressed disease state, PF = progression free state
Source: Table 2 in MSAC 1779.1 resubmission, with edits made by the department

The MSAC 1779.1 resubmission noted that the incremental cost of futibatinib treatment is $Redacted and incremental QALYs are 0.62, resulting in an ICER ($/QALY) of $75,000 to < $95,000.

The department considered that the approach for estimating the cost to identify one patient treated with futibatinib should be to divide the incremental test fee of $545 by an appropriate diagnostic yield for the proposed expanded testing population. The department noted that the MSAC 1779.1 resubmission test cost of $14,137.46 to identify one treated patient may be an over-estimate because it was derived by multiplying the initial estimate of cost per patient identified of $3,920.86 (i.e. $545 divided by an assumed diagnostic yield of 13.9%), by factors of 3.57 and 1.01 to reflect the expansion in the tested population. The approach adopted in the revised model effectively assumes a reduced diagnostic yield of 3.85% (13.8% divided by the product of 3.57 and 1.01). This may underestimate the true yield, inflate the cost per patient identified, and consequently overstate the ICER. However, while expanding the tested population should lead to a proportional increase in the total financial costs of testing (which is appropriately reflected in the financial estimates), it does not necessarily lead to an equivalent proportional reduction in the diagnostic yield and therefore does not necessarily lead to an equivalent proportional increase in cost per patient identified, as this would be contingent on data on prevalence rates and test accuracy.

[6] The Oncomine Precision Assay (OPA) NGS DNA & RNA Panel offered by Peter MacCallum Cancer Centre is for a range of genes and is not limited to *FGFR2* and *IDH1*.

The department considered that it may be more appropriate to include testing only in the CCA population in the base case, with testing in other populations addressed through sensitivity analyses. Furthermore, a better approach to estimate the combined impact of the population expansions on the cost to identify one treated patient would be to adjust the diagnostic yield accordingly to reflect prevalence rates in each of the cancer populations tested (CCA, CUP and pancreatic cancer). The department noted that in the initial submission, the applicant cited several studies, each reporting different prevalence rates of *FGFR2* fusions or rearrangements in the whole CCA population. Across these studies, the reported prevalence ranged from 3.2% to 16.9%. When data from all studies were combined, the overall average prevalence was 10.1% (1,016 out of 10,041 cases). The estimated prevalence of *FGFR2* variants in CUP and pancreatic cancer is 3.5% and 0.81% respectively.[7,8]

Including testing only in patients with CCA and an adjusted diagnostic yield of 10.1% resulted in the department revised base case ICER of $55,000 to < $75,000 At its March and July 2025 meetings, the PBAC considered that futibatinib would be cost effective with an ICER less than $55,000 to < $75,000 per QALY.

The results of sensitivity analyses in the MSAC 1779.1 resubmission and those conducted by the department are summarised in Table 3.

Table 3: Sensitivity analyses

Sensitivity analysis in the MSAC 1779.1 resubmission	**ICER**	**% change from MSAC 1779.1 resubmission base case ICER**
MSAC 1779.1 resubmission base case[a]	**Redacted[2]**	-
Multivariate analysis in MSAC 1779.1 resubmission: Assuming a test cost of $340 (consistent with MBS 73319) + testing only at 2nd line + not including testing in patients with CUP or pancreatic cancer	**Redacted[1]**	**-Redacted**%
Sensitivity analysis conducted by the department	**ICER**	**% change from department revised base case ICER**
Department revised base case: Testing at CCA diagnosis, 10.1% diagnostic yield, test fee of $885[a], 0% Omico testing at no cost, not including testing patients with CUP or pancreatic cancer	**Redacted[1]**	-
Department revised base case (as above) with test fee of $800 (consistent with gene panel for sarcoma, MBS item 73376)[b]	**Redacted[1]**	**-Redacted**%
Department revised base case (as above) with test fee of $680 (consistent with the fee of MBS item 73374 in addition to MBS item 73319 for *IDH1* testing)[c]	**Redacted[1]**	**-Redacted**%
Department revised base case (as above) including testing in patients with CUP or pancreatic cancer	**Redacted[2]**	**Redacted**%

Abbreviations: CUP = cancer of unknown primary
[a]A fee of $545 applied in the economic model ($885 - $340 [MBS fee for *IDH1* testing, MBS item 73319])
[b]A fee of $460 applied in the economic model ($800 - $340 [MBS fee for *IDH1* testing, MBS item 73319])
[c]A fee of $340 applied in the economic model ($680 - $340 [MBS fee for *IDH1* testing, MBS item 73319])
Source: Derived from MSAC 1779.1 resubmission and compiled for the departmental overview
The redacted values correspond to the following ranges:
[1]$55,000 to < $75,000
[2]$75,000 to < $95,000

[7] Cavazzoni A, Salamon I, Fumarola C, et al. Synergic activity of FGFR2 and MEK inhibitors in the treatment of FGFR2-amplified cancers of unknown primary. *Mol Ther*. 2024;32(10):3650-3668. doi:10.1016/j.ymthe.2024.07.011. The publication stated that the *FGFR2* variant prevalence to be ranging from 3-4%, therefore have estimated the prevalence to be 3.5% in the department revised calculations.

[8] Stein, L., Murugesan, K., Reeser, J.W. *et al. FGFR2*-fusions define a clinically actionable molecular subset of pancreatic cancer. *npj Precis. Onc.* **8**, 207 (2024), https://doi.org/10.1038/s41698-024-00683-x.

14. Financial/budgetary impacts

Using the values described in Section 10 above, the MSAC 1779.1 resubmission estimated costs to MBS of *FGFR2* testing to be $0 to < $10 million in year 1, increasing to $0 to < $10 million in year 6 (Table 4).

Table 4: MBS costs of *FGFR2* testing

Description	2025	2026	2027	2028	2029	2030
Net cost to the MBS[a]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]

Abbreviations: *FGFR2* = fibroblast growth factor receptor 2
[a] Assuming test fee of $885 ($545 incremental fee applied in the financial analysis), 0% free testing by Omico at no cost, testing population increased by 357% from the initial submission, an additional 1% of testing to account for testing that occurs in patients outside of the intended CCA population, 80% rebate, includes MBS offsets.
Source: Table 3 in 1779.1 resubmission
The redacted values correspond to the following ranges:
[1] $0 to < $10 million

Table 5: Revised financial analysis conducted by the department

	2025	2026	2027	2028	2029	2030
Estimated extent of use of *FGFR2* testing						
Total CCA population[a]	**Redacted** 2	**Redacted** 2	**Redacted** 2	**Redacted** 2	**Redacted** 2	**Redacted** 2
Number of patients likely to receive a positive test result[b]	**Redacted** 1	**Redacted** 1	**Redacted** 1	**Redacted** 1	**Redacted** 1	**Redacted** 1
Estimated financial implications of *FGFR2* testing and listing of futibatinib to the MBS						
Cost to MBS for *FGFR2* testing[c]	**Redacted** 4	**Redacted** 4	**Redacted** 4	**Redacted** 4	**Redacted** 4	**Redacted** 4
Cost to MBS for OCT[d]	**Redacted** 4	**Redacted** 4	**Redacted** 4	**Redacted** 4	**Redacted** 4	**Redacted** 4
Cost offset to MBS for reduction in FOLFOX[e]	**Redacted** 3	**Redacted** 3	**Redacted** 3	**Redacted** 3	**Redacted** 3	**Redacted** 3
Net cost to MBS[f]	**Redacted** 4	**Redacted** 4	**Redacted** 4	**Redacted** 4	**Redacted** 4	**Redacted** 4

Abbreviations: CCA = cholangiocarcinoma; *FGFR2* = fibroblast growth factor receptor 2; OCT = optical coherence tomography
[a] Incident population as per MSAC 1779.1 resubmission's financial spreadsheet (2a. Patients-incident worksheet)
[b] Assuming 92.5% test uptake and 10.1% diagnostic yield
[c] Based on $885 test fee (with $545 applied in the financial analysis), assuming 80% rebate
[d] Assumed to occur twice per patient; based on MBS Item 11219, with a fee of $45.50 and 80% rebate
[e] Includes Chemotherapy administration (MBS Item 13950: $123.05), insertion of a central venous access device (CVAD) (MBS item 34528, $310.35), removal of CVAD for 73.6% of patients (MBS item 34530, $232.60), anaesthesia (MBS item 20400+23010, $90.20),and cleaning the CVAD (MBS item 14221, $59.80). All assumed 80% rebate.
[f] Net cost inclusive of OCT and offset from reduction in FOLFOX administration. Does not include testing in populations outside of the intended CCA population.
Source: Compiled for the departmental overview
The redacted values correspond to the following ranges:
[1] < 500
[2] 500 to < 5,000
[3] net cost saving
[4] $0 to < $10 million

Table 6: Sensitivity analyses conducted by the department[a]

Description	2025	2026	2027	2028	2029	2030
Univariate sensitivity analyses						
Test fee of $800 (consistent with gene panel for sarcoma, MBS item 73376)[b]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]
Test fee of $680 (consistent with the fee of MBS item 73374 in addition to MBS item 73319 for *IDH1* testing)[c]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]
Test uptake in patients with CUP or pancreatic cancer						
25% test uptake	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]
100% test uptake	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]
Multivariate sensitivity analyses						
Testing at CCA diagnosis assuming a *FGFR2* diagnostic yield of 10.1% + test fee of $800[b] + 0% free testing by OMICO+ 25% test uptake in patients with CUP or pancreatic cancer	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]	**Redacted**[1]

Abbreviations: CUP = Cancer of unknown primary; *FGFR2* = fibroblast growth factor receptor 2; OCT = optical coherence tomography
[a] Note that these analyses are based on the revised financial base case calculations conducted by the department (Table 5). Net cost to the MBS is inclusive of OCT and offset from reduction in FOLFOX administration.
[b] A fee of $460 applied in the financial analysis ($800 - $340 [MBS fee for *IDH1* testing, MBS item 73319]), assuming 80% rebate
[c] A fee of $340 applied in the financial analysis ($680 - $340 [MBS fee for *IDH1* testing, MBS item 73319]), assuming 80% rebate
Source: Compiled for the departmental overview
The redacted values correspond to the following ranges:
[1]$0 to < $10 million

15. Other relevant information

Nil.

16. Applicant comments on MSAC's Public Summary Document

Nil.

17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: visit the MSAC website