MSAC REAPPLICATION TEMPLATE

Reapplication Name:	Testing of tumour tissue to detect FGFR2 fusions or rearrangements in people with cholangiocarcinoma, to determine eligibility for treatment with PBS subsidised futibatinib
Previous application number	1779
Name of previous application	Testing of tumour tissue to detect FGFR2 fusions or rearrangements in people with cholangiocarcinoma, to determine eligibility for treatment with PBS subsidised futibatinib

A. Funding Source

1. **Please check the box that corresponds with the program through which the health technology would be funded:**

☒ Medicare Benefits Schedule (MBS). Please:

a) Upload an in principle Statement of Clinical Relevance[1] when uploading this template.
b) Note in Table 2 below, any changes to the proposed MBS item(s) compared to the previous ADAR.

☐ National Blood Agreement.

☐ National Health Reform Agreement Addendum (high-cost, highly specialised therapies).

☐ National Diabetes Services Scheme.

☒ Other. Please specify the funding program:

Also, the Pharmaceutical Benefits Scheme (PBS) for futibatinib

2. **Has the funding source changed compared to your previous application?**

☒ No

B. Regulatory Information

1. Does your proposed service or technology involve (check as many as applicable):

☐ the use of a medical device, *in-vitro* diagnostic test, radioactive tracer, or any other type of therapeutic good? Please complete the section titled B1: ARTG Listing.

☒ a service or laboratory requiring accreditation by the National Association of Testing Authorities (NATA)? Please complete the section titled B2: NATA Accreditation.

☐ an MBS item descriptor that refers to a specific radiopharmaceutical or a set of radiopharmaceuticals? Please complete the section titled B3: Radiopharmaceuticals.

☐ None of the above. Proceed to the Other information section.

[1] The in principle Statement of Clinical Relevance demonstrates 'in principle' support for the proposed service. This must be from the most relevant professional medical/health group (i.e., an official college or society) that represents practitioners who would **perform** the proposed services, and (in the case of investigative technologies only) practitioners who would **request** the proposed service.

B2: NATA Accreditation

Where applicable, laboratories and other investigative service providers must be accredited by NATA. The scope of NATA accreditation must capture the service for which reimbursement is being sought.

Please provide details of NATA accreditation, clearly demonstrating that the services or technologies included in your MSAC reapplication are in-scope of the accreditation. Where accreditation is not yet in place, provide documentation demonstrating that the accreditation process is underway. Provide anticipated timeframes for the NATA accreditation decision.

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

Other Information

Please advise us if there is anything relevant to MSAC's consideration of the reapplication that is not addressed elsewhere in this template. For example, proposed major changes to the ADAR unrelated to matters of concern raised by MSAC; or the health technology is subject to a recall or other regulatory action. You can also list here any additional organisations, experts, or other stakeholders for consultation.

N/A

Table 1: Summary of key matters of concern

COMPONENT	MATTER OF CONCERN	HOW MATTER WILL BE ADDRESSED IN ADAR
Economic and financial analyses	Include testing costs for all patients diagnosed with CCA at the point of diagnosis for all economic modelling and financial impact analysis.	**Addressed** Revised economic and financial analyses to be presented
Economic and financial analyses	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).	**Addressed** Revised economic and financial analyses to be presented
Economic and financial analyses	Revise the economic and financial analyses by removing the assumption that 20% of the testing will be performed at no cost	**Addressed** Revised economic and financial analyses to be presented

Table 2: Summary of changes to PICO criteria since previous consideration by MSAC

☒ The proposed ADAR **will not** contain any changes to the PICO previously considered by MSAC.