Australian Government

Department of Health

Consultation Survey on MSAC Application 1721

Small gene panel testing for non-small cell lung carcinoma

MSAC welcomes feedback on MSAC applications for public funding from individuals, organisations representing health professionals or consumers and/or carers, and from other stakeholders. Please use this template to prepare your feedback. You may also attach additional information if you consider it may be useful in informing MSAC and its sub-committees.

Sharing consultation feedback

Submitted consultation feedback will be shared with the Applicant and with MSAC and its sub-committees.

- The applicant will receive a summary of comments from individuals, with the individual's name and other identifying information removed.
- MSAC and its sub-committees will receive both the summary and copies of the comments, with the name of the individual and other identifying information removed.
- Consultation feedback from groups or organisations will be provided in a complete form to both the Applicant and to MSAC and its sub-committees.

Please do not include information in your feedback that you do not want shared as outlined above. In addition, to protect privacy, do not include identifying personal (e.g. name) or sensitive (e.g. medical history) information about third parties, such as medical professionals or friends/relatives.

How consultation feedback is used

MSAC and its sub-committees consider consultation feedback when appraising an application, including to better understand the potential impact of the proposed medical technology/service on consumers, carers, and health professionals. A summary of consultation feedback will be included in the Public Summary Document (PSD) published on the MSAC website once MSAC has completed its appraisal. The PSD may also cite feedback from groups/organisations, including the name of the organisation. As such, organisations should not include information or opinions in their feedback that they would not wish to see in the public domain.

Consultation deadlines. Please ensure that feedback is submitted by the pre-PASC or pre-MSAC consultation deadline for this application. Consultation deadlines for each PASC and MSAC meeting are listed in the PASC and MSAC and ESC calendars available on the MSAC website. They are also published in the MSAC Bulletin. Feedback received after the respective deadlines may not be considered.

For further information on the MSAC consultation process please refer to the MSAC Website or contact the Consumer Evidence and Engagement Unit on email: commentsMSAC@health.gov.au.
Thank you for taking the time to provide your feedback. Please return your completed survey to:

Email: commentsMSAC@health.gov.au

Mail: MSAC Secretariat,
MDP 960, GPO Box 9848,
ACT 2601

PART 1 – PERSONAL AND ORGANISATIONAL INFORMATION

1. Respondent details

Name: Nick Pavlakis

Email:

Phone No:

2. Is the feedback being provided on an individual basis or by a collective group?

X Collective Group

If an individual, specify the name of the organisation you work for

If a collective group, specify the name of the group

The Thoracic Oncology Group of Australasia (TOGA)

3. How would you best identify yourself?

☐ General Practitioner
X Specialist
X Researcher
☐ Consumer
☐ Care giver
☐ Other

If other, please specify

PART 2 – CLINICAL NEED AND PUBLIC HEALTH SIGNIFICANCE

4. Describe your experience with the medical condition (disease) and/or proposed intervention and/or service relating to the application form

The Thoracic Oncology Group of Australasia (TOGA: https://thoraciconcology.org.au/) is a member-based research organisation and lung cancer and mesothelioma charity, representing the full range of professional disciplines involved in caring for patients with lung cancer, clinical trial professionals and consumer representatives.
Its membership includes a large number of clinicians involved in the treatment of lung cancer. One of the key open areas of research in clinical practice in lung cancer has been the integration of genomic information for the purpose of selecting drug therapy in specific subgroups of patients. Historically this has evolved sequentially as targeted drugs have been developed with co-dependent technology for identifying the drug targets. In Australia this has led to separate sequential applications for EGFR mutated non-small cell lung cancer (NSCLC) then ALK rearranged then ROS1 rearranged NSCLC. As such the evolutionary algorithm for molecular testing in Australia for NSCLC has been sequential individual gene testing. But as more oncogene targets with matched drug therapies have been identified, and as molecular sequencing technology has improved and become cheaper, this is a highly inefficient way to approach personalized therapy. TOGA recognised the importance of this and established a national multicentre study in 2020 - The ASPiRATION trial, an observational cohort study to assess the clinical impact of upfront comprehensive genomic profiling (CGP) on the management of patients with metastatic NSCLC (https://thoraciconcology.org.au/aspiration/). CGP is a step above the application submitted, which is looking at a limited gene panel but one that encompasses the genes for which therapies are now available in Australia. The ASPiRATION Trial is a partnership between government (MRFF Grant), industry (Roche) and Academia (TOGA, NHMRC CTC, OMICO). It aims to evaluate 1000 patients to determine the clinical benefit and value of upfront CGP compared with current standard of care testing algorithm. Since its commencement in Dec 2020, as of Aug 31, 2022, 574 patients have been enrolled in the study and have had CGP performed, using one of two platforms, Foundation Medicine and Illumina TSO500 (used in the MoST study). Although the study is ongoing, already several additional oncogene targets have been identified beyond those that would have been observed with standard testing, which since Dec 2020 has evolved from sequential single gene testing (EGFR, ALK, ROS1) to limited gene panels, currently offered ad hoc in major centres and by pathology vendors as cost. It is this limited oncogene panel that is the basis for the application that is being discussed.
TOGA acknowledges that this is an important step forward for the management of patients with NSCLC. Of course, TOGA also believes that CGP will be better still. The results of the ASPiRATION trial are hoped to provide the evidence to support this, including economic modelling.
The proposed medical service would be considered best clinical practice today.

5. What do you see as the benefit(s) of the proposed medical service, in particular for the person involved and/or their family and carers?

The benefits are:
To the patient or their family and carers: a more efficient use of their tumour biopsy samples for screening for oncogenes where current treatments exists, enabling personalised therapy with greater clinical impact for the patient. Such therapies are often oral targeted tyrosine kinase inhibitors, associated with less serious toxicity than chemotherapy, and associated with greater clinical impact (greater tumour response rate (shrinkage), prolonged progression free and/or overall survival). The existing sequential testing algorithm for EGFR, ALK, ROS1 often requires additional tissue biopsy to test for other oncogenes, which is not feasible in a substantial number of patients.
The proposed medical service reduces the need for additional biopsies which can be traumatic and costly to patients.
To the system: A more efficient diagnostic algorithm that reduces the overall need for additional scans, biopsies and laboratory tests, and enables best use of modern medicines.

6. What do you see as the disadvantage(s) of the proposed medical service, in particular for the person involved and/or their family and carers?

A disadvantage to patients is that the proposed medical service requires a minimum tissue sample that isn't always available, and as such may require the patient to be asked to have an additional biopsy. For example, the diagnosis of lung cancer can be made on a fine needle aspiration biopsy (FNAB), but the existing technology requires more than this, as can be acquired using endobronchial ultrasound (EBUS) FNA and CT-guided core biopsy. We have seen practice change over the years to focus on obtaining as much tissue as possible with the original diagnostic biopsy to avoid the need for repeat sampling. The ASPiRATION trial has been collecting data on the need for additional samples and has observed a substantial majority of original biopsies to be sufficient.

Application 1721 provides a single test option, or a two test option, with the second test only being performed if the first is negative. The two test option runs the risk of the second test not being ordered even if the first was negative (pressure to commence treatment and not wait for another test, missed (more likely in hospitals that lack lung cancer nurses of which there are several) or lack of remaining tissue/sample.

The vast majority of patients will require the second test, or in the one test option, the full panel, as the occurrence of these mutations is still relatively rare and tests are likely to come back negative, so there is unlikely to be any substantial cost saving from not requiring second tests if the two test option is employed.

People living with advanced NSCLC that are TOGA consumer representatives advocate that all testing is done in one test. Delays are distressing for patients in this initial diagnostic period before commencement of treatment, noting that many patients who present with lung cancer, and those that are most likely to have an oncogenic driver mutation identified, may have already faced a delay in referral from primary care if they do not present as a 'typical' lung cancer patient (current or ex-smoker, approaching mean age of diagnosis of 72 years).

7. What other benefits can you see from having this intervention publically funded?

The holy grail of cancer medicine is personalised therapy – choosing the treatment of best fit according to the tumour biology in a given patient. Publicly funding the proposed medical service will enable this to be offered to many more patients in an equitable fashion.

8. What other services do you believe need to be delivered before or after this intervention, eg Dietician, Pathology etc?

The intervention would fit seamlessly into the existing system. Many existing pathology vendors have already established technology platforms to implement this with standards established under the existing accreditation process (NATA). It will require a more detailed report to include the oncogene results, but these have been developed and standardised internationally, and have also been in use by services currently providing this intervention at cost.

PART 3 – INDICATION(S) FOR THE PROPOSED MEDICAL SERVICE AND CLINICAL CLAIM

9. Do you agree or disagree with the proposed population(s) for the proposed medical service as specified in Part 6a of the application form?

X Strongly Agree
☐ Agree
☐ Disagree
☐ Strongly Disagree

Specify why or why not:

The proposed medical service is in keeping with best practice and current international guidelines. To not approve it means we will lag behind using an archaic, inefficient, sequential gene testing algorithm that is no longer fit for purpose as modern therapies have developed rapidly and are available in Australia and funded on the PBS, as outlined in Table 2. Note several PBAC applications are in progress eg. tepotinib for metExon14, sotorasib for KRASG12C mutations, whilst others are in clinical trial (eg. RET and other KRAS inhibitors in lung cancer)

10. Have all the associated interventions been adequately captured in Part 6b of the application form?

X Yes
☐ No

Please explain:

These are clearly outlined in point 27.

11. Do you agree or disagree that the comparator(s) to the proposed medical service as specified in Part 6c of the application form?

X Strongly Agree
☐ Agree
☐ Disagree
☐ Strongly Disagree

Please explain:

These are clearly outlined in point 38.

12. Do you agree or disagree with the clinical claim made for the proposed medical service as specified in Part 6d of the application form?

X Strongly Agree
☐ Agree
☐ Disagree
☐ Strongly Disagree

Specify why or why not:

Agree strongly with comments in point 43 and 45.

PART 4 – COST INFORMATION FOR THE PROPOSED MEDICAL SERVICE

13. **Do you agree with the proposed service descriptor?** MSAC is transitioning to new application forms so the relevant question in the application form will vary depending on the version used. For medical services on the MBS, see question 51 or 53. For medical services seeking funding from a source other than the MBS, see question 52 (new application forms only—labelled v. 2.5).

X strongly Agree
☐ Agree
☐ Disagree
☐ Strongly Disagree

Specify why or why not:

The descriptor provided under point 53 is appropriate and fit for purpose.

14. **Do you agree with the proposed service fee?** MSAC is transitioning to new application forms, so the relevant question in the application form will vary depending on the version used. For medical services on the MBS, see question 51 or 53. For medical services seeking funding from a source other than the MBS, see question 52 (new application forms only—labelled v. 2.5).

X Strongly Agree
☐ Agree
☐ Disagree
☐ Strongly Disagree

Specify why or why not:

TOGA supports the recommendations for fee structure proposed by the Royal College of Pathologists Australasia (RCPA), but isn't in a position to offer critical appraisal on the costing directly.

PART 5 – ADDITIONAL COMMENTS

15. Do you have any additional comments on the proposed intervention and/or medical condition (disease) relating to the proposed medical service?

The proposed lung cancer specific limited gene panel would be considered modern standard of care and is a necessary evolution from our current inefficient algorithm of sequential individual gene testing. The intervention is in practice in many parts of the world and is recommended unanimously in international guidelines.

TOGA strongly supported the application and is itself undertaking a clinical trial (The ASPiRATION trial) to evaluate the value of even broader testing in the Australian context

16. Do you have any comments on this feedback survey? Please provide comments or suggestions on how this process could be improved.

Again, thank you for taking the time to provide valuable feedback.