Consultation Survey on MSAC Application 1726

Testing of tumour tissue to determine a positive homologous recombination deficiency status in women newly diagnosed with advanced (FIGO stage III-IV) high grade epithelial ovarian, fallopian tube or primary peritoneal cancer, for access to PBS niraparib

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: Dr Matilda Haas

Email: matilda.haas@mcri.edu.au

Phone No: 0403287727

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

☐ Individual
☒ Collective Group

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

If a collective group, specify the name of the group

Australian Genomics

3. How would you best identify yourself?

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

If other, please specify

Research Projects and Partnership Manager submitting a response on behalf of Australian Genomics in consultation with researchers and senior administration.
Please note this response has been prepared by generalist health and medical research professionals with experience in genetics/genomics and cancer research, but not in the specific area of oncology that is the subject of this application.

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

Australian Genomics is an Australian Government initiative supporting genomic research and its translation into clinical practice. Through broad engagement and a national collaborative approach, it achieves two key objectives: to improve efficiency, reach and timeliness of genomic research projects, and to support Commonwealth State and Territory health departments in the implementation of genomics research outcomes by refining and communicating evidence to inform policy development.

Australian Genomics engages with current and emerging government policy and priorities to identify gaps and opportunities, to support policy and action for integrating genomic technologies into the health system. By interfacing with consumers, governments, industry and global genomics initiatives, Australian Genomics drives change and growth in the sector.

Australian genomics has investigated clinical implementation of genomic testing into a range of rare disease and cancer diseases. This has included a Somatic flagship, that investigated clinically actionable variants in a range of cancer types using the Comprehensive Cancer Panel (391 cancer gene panel) at the Peter MacCallum Cancer Centre. This study, on non-resectable solid tumours also investigated the implementation of treatment changes in patients after their genomic result.

Additionally, the Hereditary Cancer Syndromes flagship utilised whole genome sequencing to investigate causative variants in a range of familial cancers, providing additional treatment and management option for families. This work made use of the ICCon network of Familial Cancer Centres and researchers.

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?

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?

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

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

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?**

- ☐ Strongly Agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly Disagree

Specify why or why not:

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

- ☐ Yes
- ☐ No

Please explain:

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

- ☐ Strongly Agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly Disagree

Please explain:

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?**

- ☐ Strongly Agree

☐ Agree
☐ Disagree
☐ Strongly Disagree

Specify why or why not:

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).

- ☐ Strongly Agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly Disagree

Specify why or why not:

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).

- ☐ Strongly Agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly Disagree

Specify why or why not:

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?

In our response to the original submission of MSAC application 1658 "Testing of tumour tissue to determine a positive homologous recombination deficiency (HRD) status in women newly diagnosed with advanced (FIGO stage III-IV) high grade epithelial ovarian, fallopian tube or primary peritoneal cancer for access to PBS Olaparib", which is also based on a HRD test, Australian Genomics outlined concerns that there was not enough information about the methodology or utility of HRD test for stakeholders to review the application effectively. The current application proposes the use of a HRD test to inform eligibility for access to Niraparib for the same cancer type. This application also provides little information about the test itself (aside from Q6 on page 2), and we have not been able to source any further information about the test (which was proposed to have been released in Australia in August 2022 - page 5). Given the reopening of 1658 as 1658.1, test validation and accreditation are likely drawing closer, however, without access to further information it is difficult for stakeholders to comment on this application beyond perspectives already submitted in response to 1658.

This application also states that HRD testing is expected to "entirely replace" BRCA1/2 testing for populations #1 (tumour testing at diagnosis) and #3a (tumour testing at primary chemotherapy). This suggestion should be supported by evidence including health economic evidence, cost savings, whether it represents the most efficient use of tumour material, and patient experience. Another potential concern with the test is the evidence presented from studies 3 and 4 in Part 4 – Summary of Evidence. The studies show concordance of around 90% between different tests (Myriad, Illumina) which does not seem to support a high degree of accuracy.

As discussed by the applicants in response to Q43, to support the clinical claim for the test, comparison with the Myriad test, analytical performance, clinical utility and validity, failure rates, turnaround times and safety will need to be demonstrated.

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.