# Consultation Survey on MSAC Application 1658.1

## 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 olaparib

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: 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**

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:**

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| |

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

- ☐ Yes
- ☐ No

**Please explain:**

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**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:**

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**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:**

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# 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:**

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|---|
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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:**

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|---|
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# 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 application 1658.1 is a reconsideration of 1658 that was initially not supported by MSAC (in July 2022). Australian Genomics considers key points from the Public Summary Document to include:

- *"further information is needed to elucidate how to confidently identify ovarian tumour tissue as being homologous recombination deficient. Currently HRD status has not yet been satisfactorily defined by reference to a single test method, scoring algorithm and threshold", and*

- *"across medicines in the same class as olaparib, there is equivocal evidence regarding how well the extent of response to olaparib is predicted by a tumour being classified as HRD positive without a pathogenic variant in the BRCA1/2 genes", and*

- *"the way each of the two HRD tests work is also secret (called a "black box" algorithm) and MSAC considered that this lack of transparency was important because it would hinder quality assurance of the test results"*

Australian Genomics anticipates that as MSAC previously chose not to recommend the service, that new evidence/validation studies have now been made available to MSAC covering each of these issues and others, specifically in relation to the equivalence of the SOPHiA Genetics assay to the Myriad assay. However, the updated application form provided to stakeholders for consultation does not provide further information on which to re-assess the medical service, particularly in relation to the concerns raised in the PSD.

At the time, in response to application 1658 Australian Genomics submitted:

*"The evidence base for this test is complicated, not entirely supportive, and seems to be the subject of ongoing controversy in oncology (Pellegrino et al., 2019). HRD is complex and dynamic in nature, and with several different types of test being developed, yet no functional assay, it can be difficult to interpret the current available evidence on utility, although recent recommendations cited in the application are available (eg Miller et al., 2020)."*

*"It is also not clearly stated in this version of the application what kind of test is being proposed here (ie what does the genomic instability test involve?)…If the test is approved but without clarity on the methodology, it does not give other providers the opportunity to develop similar tests, affecting accessibility, nor allow a competitive environment to improve upon the test. The application notes that there may be a period of 1-2 years where only the proposed testing service will offer the test in Australia – prior to either other commercially available kits, or the development of the test in other Australian diagnostic laboratories which would have considerable risk of monopoly pricing, especially in the context of the REDACTED proposed cost."*

*"The other limitation is that HRD testing is currently done only in the context of determining whether PARP inhibitors are going to be useful, which may indicate limited utility due to decreased applicability to other inhibitors of key targets of Homologous Recombination Repair (HRR)."*

*"There is also the question about developing resistance to PARP inhibitors, so overprescribing or mis-prescribing should be avoided, since it seems to be a powerful option when used in specific contexts."*

*"In the absence of better available tests, MSAC needs to weigh up whether approving this test now will do more good than harm, while potentially in future there may be better, more accurate tests available."*

*"However, it should be noted that the HRD as an indicator for PARP inhibitor use has been approved by the FDA and Pellegrino et. al., do surmise the current information to conclude that for ovarian cancer, HRR status can inform patients who will receive maximum benefit from PARP inhibitor maintenance after platinum therapy."*

A further consideration is the similar application by GSK is being now being considered: "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". For 1726 GSK is using the PICO framework put forward by AZ in 1568, with modifications outlined in the 1658 PSD. It is also noted that while 1568 did not propose a fee for the service it used a costing of $2500 for economic evaluations, and 1726 has subsequently put forward a fee of $3000. The relationship between the two applications makes it difficult for stakeholders to provide comment.

Without further information, Australian Genomics offers no further comment on the proposed medical service.

**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.**