Consultation Survey on MSAC Application 1765

Amendment of MBS items 73303 and 73304 (BRCA1/2 mutation testing in patients with metastatic castration-resistant prostate cancer) to include talazoparib

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

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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

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, research and timelines 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, government, industry and global genomics initiatives, Australian Genomics rives change and growth in the sector.

Australian Genomics has investigated clinical implementation of genomic testing into a range of rare diseases and cancer. Between 2016 and 2020 Australian Genomics flagships recruited 2768 participants with cancer to have genomic sequencing. These flagships included somatic and hereditary cancer projects that investigated clinically actionable variants in a range of cancer types (Stark et al., 2023).

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 proposed medical service is for identification of patient eligibility for clinically appropriate treatment with the PARP inhibitor talazoparib. The application is for an amendment of existing item numbers (73303 and 73304) which provide tumour and germline testing for BRCA gene variants to determine eligibility for treatment with another PARP inhibitor, olaparib. The amendment is to include talazoparib as an alternative treatment.

This service could be expected to be accessed by up to 4,844 patients annually (based on 24,217 documented prostate cases in Australia in 2023 (AIHW 'Cancer Data in Australia') of which 10-20% are estimated to progress so castration resistant prostate cancer within 5 years (Kirby et al., 2011). There have been reports of a higher proportion of prostate cancers being castration resistant. For example, Akaza et al. (2018), quoted a figure of 10-50%. However, a more realistic estimation may be inferred by usage rates of the current item numbers: MBS item 73303 was accessed 1183 times and 73304 416 times from July 2022 to June 2023.

Access to this alternative PARP-inhibitor would offer considerable hope for the patient, family members and carers and offer a better quality of life. In a clinical trial, talazoparib was shown to have an anti-tumour effect with early data indicating that the treatment lengthens progression free survival (Agarwal et al., 2023)**.**

As outlined in the current TALAPRO-2 trial publication (Agarwal et al., 2023), there may be differences in the effectiveness of different PARP inhibitors depending on dosing and HRR gene alteration status in the patient, and so it is critical to have a range of PARP inhibitors available so that the best treatment choice can be made for each individual patient.

If access to the treatment was not made available there would be an inequity of access in providing Australians the best standard of care for this condition.

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?

In the phase 3 clinical trial of talazoparib plus enzalutamide in men with metastatic castration-resistant prostate cancer, treatment-emergent adverse events were outlined. These included anaemia, neutropenia and fatigue. It was noted in the study that these adverse effects improved after dose reduction.

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

The proposed service will add to the available treatment options for metastatic castration-resistant prostate cancer. The proposed testing, in combination with the treatments listed on the Pharmaceutical Benefits

Scheme will result in a considerable lessening of financial burdens to the patient and their families. Additionally, there may be a reduction in cost to the health services involved and an increase in patient quality adjusted life years, although this would require further long-term investigation.

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

The proposed intervention will mainly be facilitated by medical oncology clinicians in the first instance, for tumour testing of prostate tissue where available. There may be referrals to genetic services for further germline and family testing where appropriate.

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:

We note the population is patients who have not been previously treated with a novel hormonal agent.

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

- ☒ Yes
- ☐ No

Please explain:

A regime of talazoparib and enzalutamide is consistent with the referenced phase 3 trial (Agarwal et al., 2023). We note that enzalutamide is the current standard of care as first-line treatment for patients with BRCA1/2 gene mutations.

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:

Supplementary comparator 2 is listed as abiraterone monotherapy. In a study of comparative effectiveness of abiraterone and enzalutamide in metastatic castration-resistant prostate cancer patients, it was found that there was a similar overall survival rate (Li et al., 2022).

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:

As indicated in Agarawal et al., (2023) further follow-up of both survival data and long-term safety follow-up is strongly encouraged in this cohort.

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

Please explain:

The descriptor as written would clearly describe the two PARP inhibitors for which the test result informs eligibility.

However, this application raises the need to consider whether the descriptor needs to provide specific drug names. As more PARP inhibitors (or indeed other classes of drugs for other conditions) from different pharmaceutical companies become available, further amendments to the relevant MBS item numbers will become burdensome. The wording could be changed to "inform eligibility to a PBS approved PARP inhibitor". This would reduce the administrative burden for MSAC in relation to ongoing amendments to item numbers linking diagnostic tests to specific drugs.

The NHS Genomic Test Directory cancer directory includes a somatic test for detection of BRCA1 and BRCA 2 variants in metastatic, castration-resistant prostate cancer (M218.1), and in the case of failure of that test the rare and inherited disease directory includes a test for germline analysis using a small panel prostate cancer test for BRCA 1 and BRCA 2 variants (R444.2). These tests inform eligibility to access a "NICE approved PARP inhibitor treatment" and this wording could be adopted by the MBS. However, it should be acknowledged in this discussion that at this stage NICE has approved only one PARP inhibitor, olaparib, for prostate cancer so far.

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

There are several MBS items numbers (and MSAC applications) associated with genetic testing for BRCA1/2 gene variants for different indications where various MBS reimbursement rates have been applied, for example, 73304 ($1000) and 73295 ($1200). It is our view that for consistency of this intervention the reimbursement should be standardised for similar genetic tests.

We acknowledge that MSAC expects that as the costs of genetic and genomic tests go down over time there is a case for applying lower rebates to new tests. However, there should be a mechanism to review currently available item numbers as a continuous process. Without this, implications for service delivery will be observed with the ultimate downstream effect of substantial out-of-pocket gap payments by patients, leading to inequity for those who would benefit from accessing these tests and therapies, but cannot afford them.

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?

There may be workforce implications associated with the availability of this test, due to an increase in tumour BRCA1/2 mutation testing by medical oncology services due to greater awareness of the treatment options for this condition. This may lead to downstream increase in referrals to clinical genetic services and increased laboratory panel/gene testing. Any increased workload would need to be modelled, and managed to ensure turnaround times remain short enough so that results can be efficiently incorporated into the treatment pathway/management of the patient.

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

A review of the formatting of the survey document would be appreciated by those providing consultation feedback.

REFERENCES

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