Australian Government
Medical Services Advisory Committee
Protocol Advisory Sub-committee

Feedback Survey

Application 1380 - Germline BRCA mutation testing to determine eligibility for olaparib maintenance therapy in patients with platinum-sensitive relapsed ovarian cancer (including fallopian tube or primary peritoneal cancer) with high grade serous features or a high grade serous component

Thank you for taking the time to complete this feedback form on a draft protocol to consider the options by which a new intervention might be subsidised through the use of public funds. You are welcome to provide feedback from either a personal or group perspective for consideration by the Protocol Advisory Sub-Committee (PASC) of MSAC when the draft protocol is being reviewed.

The data collected will be used to inform the MSAC assessment process to ensure that when proposed healthcare interventions are assessed for public funding in Australia, they are patient focused and seek to achieve best value.

This feedback form should take 10-12 minutes to complete.

You may also wish to supplement your responses with further documentation or diagrams or other information to assist PASC in considering your feedback.

Responses will be provided to the MSAC, its subcommittees and the applicant with responses identified unless you specifically request de-identification.

While stakeholder feedback is used to inform the application process, you should be aware that your feedback may be used more broadly by the applicant.

Please reply to the HTA Team

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Fax: 02 6289 3561

Phone 02 6289 7550

Email: HTA@health.gov.au

Your feedback is required by **cob 14 November 2014** to enable the responses to be provided to PASC when it reviews this protocol at its meeting of 11-12 December 2014.

PERSONAL AND ORGANISATIONAL INFORMATION

1. What is your name? **Cancer Voices Australia**

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

❑ Individual

❑ **Collective group**. Specify name of group (if applicable) **Cancer Voices Australia (CVA)**

3. What is the name of the organisation you work for (if applicable)? **Cancer Voices Australia (CVA)**

4. What is your e-mail address? **info@cancervoicesaustralia.org**

5. Are you a:
    a. General practitioner
    b. Specialist
    c. Researcher

d. Consumer
e. Care giver
f. Other (please specify) **Consumer organisation**

MEDICAL CONDITION (DISEASE)

Ovarian cancer is the tenth most common cancer in Australian women, and the second most common gynaecological cancer.
As the symptoms for ovarian cancer tend to be vague and non-specific, a relatively high proportion of diagnoses occur at an advanced stage, leading to lower survival rates. In the period between 2006-2010, the 5-year relative survival rate for ovarian cancer was 43% (AIHW, *Gynaecological cancers in Australia: an overview*, 2012).

PROPOSED INTERVENTION

Olaparib has been shown to improve progression-free survival when used as maintenance therapy in women with platinum-sensitive relapsed ovarian cancer (including fallopian tube or primary peritoneal cancer) with high grade serous features or a high grade serous component. Platinum sensitivity is defined as complete or a partial response to the most recent platinum-based chemotherapy and a subsequent platinum-free interval of six months or longer.

The current application seeks funding for germline BRCA mutation testing to determine eligibility for olaparib maintenance therapy for women with the abovementioned form of ovarian cancer. The application proposes that patients who test as germline BRCA mutation positive (BRCA1 or BRCA2) will be eligible for olaparib maintenance therapy, while those who test as germline BRCA mutation negative will continue to receive standard follow-up care.

CLINICAL NEED AND PUBLIC HEALTH SIGNIFICANCE

1) Describe your experience with the medical condition (disease) and/or proposed intervention relating to the draft protocol?

   CVA has (and has had) a number of members with ovarian cancer. We also have many members with a BRCA mutation. We understand, from the consumer perspective, the generally terrible path for woman diagnosed with ovarian cancer and the difficulties faced by people and their families when deciding whether to undertake BRCA testing.

2) What do you see as the <u>benefits</u> of this proposed intervention for the person involved and/or their family and carers?

   CVA considers that BRCA testing should be open to, and freely available for, anyone who might benefit from it. That may mean women with ovarian cancer who want to know their status for their purpose of obtaining a particular treatment. It may also mean other people more generally, so they are able to make informed decisions about preventive action.

   An obvious spin-off benefit for this intervention is increased awareness in relatives of the woman with ovarian cancer, giving them information on which to make their own health decision. Ultimately, more

people being aware of a genetic mutation will reduce medical and related costs as the incidence of cancer reduces.

A particular benefit is also that the relevant woman would be aware of her increased risk of breast cancer and so able to undertake breast cancer surveillance etc.

We note though that the national guidelines provide that all women diagnosed with ovarian cancer aged under 70 should be referred for BRCA testing. CVA agrees with these guidelines and believes acceptance of this application will help to strengthen adherence to that guideline.

Although this is an application only for the BRCA testing component, it is impossible to talk about the benefits of this intervention without also considering the benefits of olaparib. There has been very little advance in the treatment of women with ovarian cancer for twenty years. With recent studies indicating that ovarian cancer is not a single disease but instead many diseases, some actually not even starting in the ovary, CVA supports the move to more targeted treatments so that women are offered appropriate treatment for their sub-type of ovarian cancer. It seems the only way survival rates will improve. Therefore we support the development of olaparib as a treatment that has shown good effect in trials and which is well tolerated by women. It is certainly better tolerated than chemotherapy, which means women living with ovarian cancer will have a better quality of life with it than without it. Obviously also the fact olaparib is a pill means it is a very convenient way for women to have the drug and will dramatically reduce the need for women to attend hospitals to have treatment, which would also substantially reduce costs to the medical system. Our members with ovarian cancer definitely consider the option of having olaparib to extend their progression free survival as an enormous and important opportunity.

3) What do you see as the <u>disadvantages</u> of this proposed intervention for the person involved and/or their family and carers?

The only disadvantage CVA is aware of regarding the proposed intervention is the possible distress caused to family members who may consequently later learn they have a mutation, or possible feelings of guilt for the woman herself, if the test is positive and she has passed it on to her children. While we acknowledge this is a real issue, it is not a reason to stop approval. The upside of that is of course greater awareness of a real and present risk and the opportunity to take action to lessen that risk so the benefits of increased knowledge outweigh these possible issues. It also should be noted that if the national guidelines were universally followed, these women would be tested anyway, so there should not actually be any increase. Of course it is up to a woman's choose whether to have this BRCA testing, in any case. Our members clearly consider the test should be available and publicly funded to women who want to have it.

4) How do you think a person's life and that of their family and/or carers can be improved by this proposed intervention?

Obvious benefits include increased awareness among family members of the woman undergoing the testing, giving them information on which to make their own decisions, and the subsequent reduction in cancer incidence and consequent reduction in healthcare and other costs to the community.

For the women concerned, having access to a drug which will give them at the very least an increased quality of life during treatment is of enormous benefit. For most it will also improve their progression free survival. This is of enormous significance to our members with ovarian cancer.

5) What other benefits can you see from having this proposed intervention publicly funded on the Medicare Benefits Schedule (MBS)?

CVA strongly believes this testing should be publicly funded because a woman's ability to have the test and therefore be eligible for this drug should not be dependent on her ability to pay for it. The long term savings to the government will more than justify the initial outlay in paying for the testing.

INDICATION(S) FOR THE PROPOSED INTERVENTION AND CLINICAL CLAIM

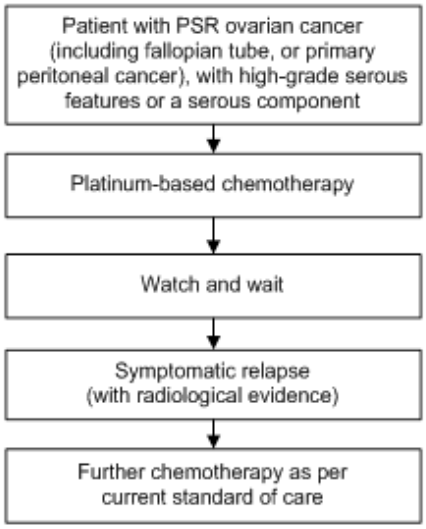
Flowchart of current management and potential management with the proposed intervention for this medical condition.

The current treatment for ovarian, fallopian tube or primary peritoneal cancer is primary cytoreductive surgery followed by intravenous platinum-based chemotherapy. A high proportion of patients relapse and require re-treatment within 12 to 18 months. Upon relapse, these women are typically re-treated with platinum agents. After re-treatment, patients are monitored and only considered for another course of treatment if they progress and develop clinical signs or symptoms that are indicative of a subsequent relapse.

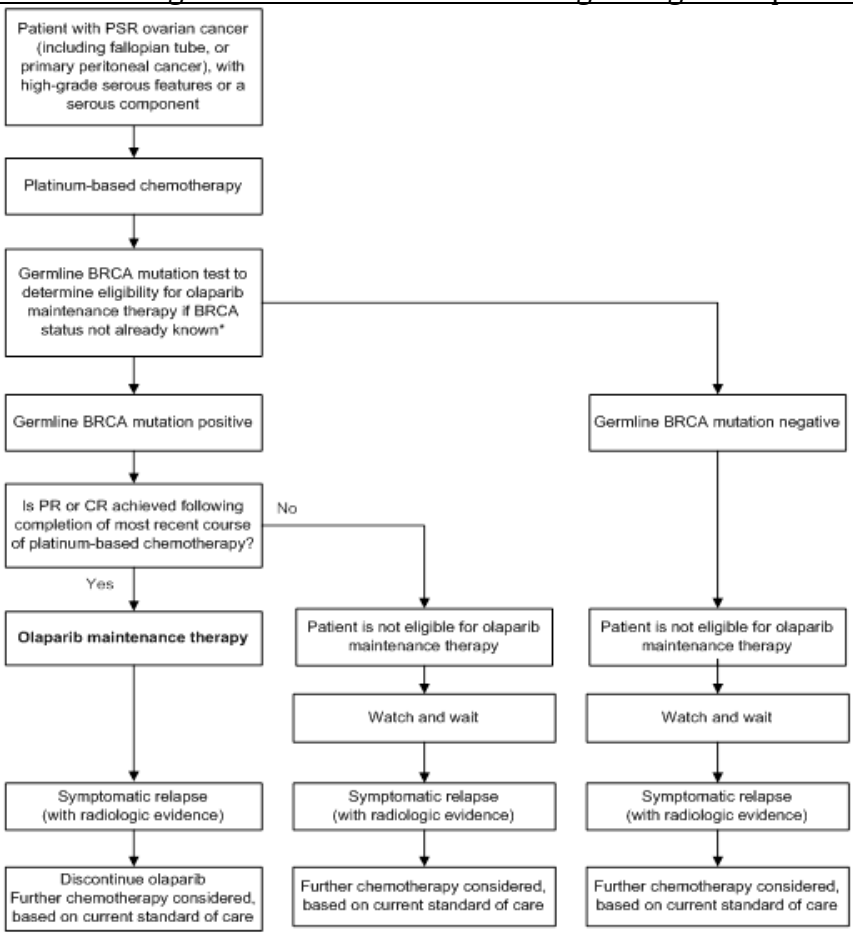
The application proposes that patients who show a partial or complete response to the most recent course of platinum-based chemotherapy and are found to be germline BRCA mutation positive should be eligible for olaparib maintenance therapy.

The application proposes two alternative management scenarios for testing of the germline BRCA mutation to determine eligibility for olaparib: 1) testing during the subsequent course of chemotherapy; or 2) testing following completion and a response (partial or complete) to the subsequent course of platinum-based chemotherapy. These two scenarios are set out in the flowcharts below.

Current Management



Proposed Management Scenario 1: germline BRCA mutation testing during subsequent course of chemotherapy



Proposed Management Scenario 2: germline BRCA mutation testing following completion of chemotherapy

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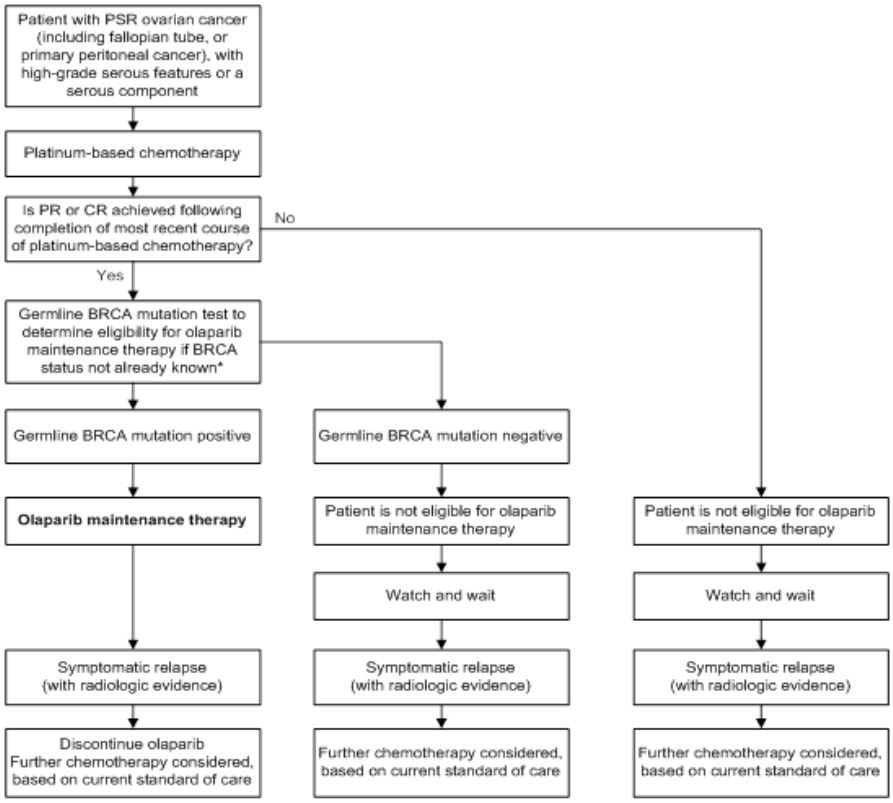

1.

6) Do you agree or disagree with the eligible population for the proposed intervention as specified in the proposed management flowcharts?

❑ **Strongly agree**
❑ Agree
❑ Disagree
❑ Strongly disagree

Why or why not?

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7) Do you agree or disagree with the comparator for the proposed intervention as specified in the current management flowchart?

❑ **Strongly agree**
❑ Agree
❑ Disagree
❑ Strongly disagree

Why or why not?

The current treatment is to wait and see. There is nothing else publicly funded for women to go on after their second relapse.

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8) Do you agree or disagree with the clinical claim (outcomes) made for the proposed intervention?

❑ **Strongly agree**
❑ Agree
❑ Disagree
❑ Strongly disagree

Why or why not?

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9) Have all associated interventions been adequately captured in the flowchart?

❑ **Yes**
❑ No

If not, please move any misplaced interventions, remove any superfluous intervention, or suggest any missing interventions to indicate how they should be captured on the flowcharts. Please explain the rationale behind each of your modifications.

ADDITIONAL QUESTIONS FOR PASC SPECIFIC TO THIS PROPOSAL

ADDITIONAL COMMENTS

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

CVA would support scenario 1 over scenario 2. These women are aware what's coming for them. They know they are very likely to die from this disease and are looking to live as long as they can, as well as they can. It would better to have the BRCA testing, if it has not been done already as per the national guidelines, as early as possible. Waiting until the end of treatment may mean a delay in beginning olaparib. It also means a delay in the woman being able to make a decision about what treatment she WANTS to undergo after her second platinum treatment. It gives her more time to discuss all treatment options with her medical team and family and to investigate trial options etc and then decide the best course for her. While eligibility for olaparib will depend on her response to platinum therapy, to delay the testing means the woman is without highly relevant information while considering all of this and has to wait for the test results.

Also, earlier testing of the woman means earlier awareness for her in relation to breast cancer risk and for her family members for both breast and ovarian cancer risk and a chance for them to take earlier preventative action. That time may make an enormous difference in whether someone gets breast or ovarian cancer at all, or even the stage at which it is detected. The earlier it is detected, the better the prognosis for that family member.

CVA supports the national guidelines and clinical best practice of offering women with ovarian cancer BRCA testing during their FIRST chemotherapy regime. If this has not been done, it should be offered while she is

undergoing her second. There is no reason to delay many months until after she has completed her second chemotherapy regime.

11) Do you have any comments on this feedback form and process? Please provide comments or suggestions on how this process could be improved.
As this is a companion application to one for approval of olaparib, it would be useful if we were asked to comment on both together. It has been difficult to distinguish between the two as they are so linked.

Thank you again for taking the time to provide your valuable feedback.

If you experience any problems completing this on-line survey please contact the HTA Team

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