Expansion of *BRCA1* and *BRCA2* germline variant testing item for patients with HER2 negative breast cancer – Amended item 73295

Last updated: 31 May 2024

- From 1 July 2024, one Medicare Benefits Schedule (MBS) item (73295) will be amended to expand eligibility for germline testing *BRCA1* or *BRCA2* status in patients with breast cancer to include people with triple-negative early breast cancer (TNBC) or hormone receptor (HR)-positive, HER2-negative early breast cancer with high-risk characteristics of high-grade tumour.
- Item 73295 will remain available for the detection of germline *BRCA1* or *BRCA2* pathogenic or likely pathogenic gene variants, in a patient with advanced (FIGO III-IV) high-grade serous or high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer for whom testing of tumour tissue is not feasible.
- This change is relevant for specialists, consultant physicians and pathologists who manage patients with these cancers.
- The purpose of the test is to determine eligibility for access to poly-ADP ribose polymerase (PARP) inhibitor therapy under the Pharmaceutical Benefits Scheme (PBS).
- The item is being expanded as an additional subgroup of patients may be identified that may benefit from or are more likely to respond to a PARP inhibitor.

What are the changes?

Effective 1 July 2024, MBS item 73295 will be amended to support an additional subgroup of patients for germline testing of BRCA1 and BRCA2 status.

Item 73295 will enable specialists and consultant physicians to request the determination of BRCA1 or BRCA2 gene variants in patients with newly diagnosed advanced or metastatic high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer, people with triple-negative early breast cancer (TNBC) or hormone receptor (HR)-positive, HER2-negative early breast cancer with high-risk characteristics of high-grade tumour.

Item 73295 will remain available for the detection of germline *BRCA1* or *BRCA2* pathogenic or likely pathogenic gene variants, in a patient with advanced (FIGO III-IV) high-grade serous or high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer for whom testing of tumour tissue is not feasible.

Item 73295 is applicable once per lifetime.

For private health insurance purposes, item 73295 will continue to be listed under following clinical category and procedure type:

- Clinical category: Support list (pathology)
- Procedure type: Type C

Attachment A contains additional information concerning the new item.

Why are the changes being made?

In Australia, breast cancer is the most common cancer affecting women. Amending test will support identification of an additional subgroup of breast cancer patients who may benefit from or are likely to respond to treatments with PARP inhibitor therapies listed under the PBS. Germline *BRCA1* or *BRCA2* pathogenic variants would support some patients to access PARP inhibitors listed under the PBS.

At its November 2023 meeting, the Medical Services Advisory Committee (MSAC) recommended expanding MBS item 73295 to include people with TNBC or HR-positive, HER2-negative early breast cancer with high-risk characteristics of high-grade tumour to determine eligibility for treatment with a PARP inhibitor, under Application 1716.1. Further details about MSAC applications can be found under MSAC Applications on the MSAC website (Medical Services Advisory Committee).

MSAC considered that it was appropriate for the eligible testing population of the amended item to remain broader than the eligible population for PBS-subsidised olaparib, a PARP inhibitor, as aligning the two populations may lead to delays in treatment initiation.

The Pharmaceutical Benefits Advisory Committee (PBAC) supported the expansion of the listing for Olaparib on the PBS for breast cancer patients who are:

- early stage and either negative for HER2 expression and HR-positive, or negative for both and,
- are undergoing neoadjuvant or adjuvant chemotherapy and adjuvant to surgical resection and,
- have a tumour linked with a *BRCA1* or *BRCA2* mutation and,
- considered to have a high risk of recurrence.

High risk is defined by any of the following:

- A triple-negative breast cancer patient with residual disease after previous neoadjuvant chemotherapy or,
- A triple-negative breast cancer patient with a substantial tumour burden after adjuvant chemotherapy or,
- A hormone receptor-positive, HER2-negative patient with residual disease after neoadjuvant chemotherapy, or with 4 or more positive lymph nodes after adjuvant chemotherapy.

What does this mean for requesters and providers?

From 1 July 2024, specialists and consultant physicians will be able to request MBS funded testing to determine germline *BRCA1* and *BRCA2* status for triple negative or HER2 negative & HR positive breast cancer patients to determine eligibility for treatment with a PARP inhibitor under the PBS.

To be eligible for Medicare benefits, laboratories providing this service must be accredited according to the pathology accreditation standards specified in the *Health Insurance (Accredited Pathology Laboratories-Approval) Principles 2017*.

How will these changes affect patients?

The listing of this service will identify more patients with breast cancer that will benefit from PARP inhibitor therapy and will allow them to access subsidised treatment under the PBS.

Who was consulted on the changes?

Consultation has been undertaken with Pink Hope, The Medical Oncology Group of Australia (MOGA), The Royal College of Pathologists of Australasia (RCPA), Australian Genomics (AG) and Omico as part of the MSAC process.

How will the changes be monitored and reviewed?

All MBS items are subject to compliance processes and activities, including random and targeted audits which may require a provider to submit evidence about the services claimed.

Where can I find more information?

The full item descriptor(s) and information on other changes to the MBS can be found on the MBS Online website at www.mbsonline.gov.au. You can also subscribe to future MBS updates by visiting MBS Online and clicking 'Subscribe.'

The Department of Health and Aged Care provides an email advice service for providers seeking advice on interpretation of the MBS items and rules and the *Health Insurance Act 1973* and associated regulations. If you have a query relating exclusively to interpretation of the Schedule, you should email askMBS@health.gov.au.

Private health insurance information on the product tier arrangements is available at www.privatehealth.gov.au. Detailed information on the MBS item listing within clinical categories is available on the Department's website. Private health insurance minimum accommodation benefits information, including MBS item accommodation classification, is available in the latest version of the *Private Health Insurance (Benefit Requirements) Rules 2011* found on the Federal Register of Legislation. If you have a query in relation to private health insurance, you should email PHI@health.gov.au.

Subscribe to 'News for Health Professionals' on the Services Australia website and you will receive regular news highlights.

If you are seeking advice in relation to Medicare billing, claiming, payments, or obtaining a provider number, please go to the Health Professionals page on the Services Australia website or contact the Services Australia on the Provider Enquiry Line – 13 21 50.

The data file for software vendors when available can be accessed via the Downloads page.

Attachment A: New item descriptor (to take effect 1 July 2024)

Category 6 – Pathology Services

Group P7 – Genetics

73295

Detection of germline *BRCA1* or *BRCA2* pathogenic or likely pathogenic gene variants, requested by a specialist or consultant physician, to determine eligibility for treatment with a poly (adenosine diphosphate [ADP]-ribose) polymerase (PARP) inhibitor under the Pharmaceutical Benefits Scheme (PBS), in a patient with:

(a) advanced (FIGO III-IV) high-grade serous or high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer for whom testing of tumour tissue is not feasible; or

(b) triple negative early breast cancer; or

(c) hormone receptor positive, *HER2*-negative, early breast cancer with one or more high-risk characteristics.

Applicable once per lifetime.

Fee: $1,200.00
Benefit: 75% = $900.00 85% = $1,101.30

(See para PN.0.23 of explanatory notes to this Category)

Explanatory note PN.0.23

Patients who are found to have any form of affected allele should be referred for post-test genetic counselling as there may be implications for other family members. Appropriate genetic counselling should be provided to the patient either by the specialist treating practitioner, a genetic counselling service or a clinical geneticist.

Please note that the information provided is a general guide only. It is ultimately the responsibility of treating practitioners to use their professional judgment to determine the most clinically appropriate services to provide, and then to ensure that any services billed to Medicare fully meet the eligibility requirements outlined in the legislation.

This factsheet is current as of the Last updated date shown above and does not account for MBS changes since that date.