Homologous recombination deficiency testing of patients with ovarian, fallopian tube or peritoneal cancer – new item 73307

Last updated: 15 December 2023

- From 1 January 2024, one new Medicare Benefits Schedule (MBS) item will be introduced to determine homologous recombination deficiency (HRD) status, including *BRCA1* or *BRCA2* status, of tumour tissue in patients with newly diagnosed advanced or metastatic high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer.
- 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), as HRD testing identifies an added subgroup of patients that may benefit from or are more likely to respond to a PARP inhibitor.
- This change is relevant for specialists, consultant physicians and pathologists who manage patients with ovarian, fallopian tube or primary peritoneal cancer.

What are the changes?

Effective 1 January 2024, new MBS item 73307 will be introduced to support testing of HRD status (including *BRCA1* and *BRCA2* status) of tumour tissue.

Item 73307 will enable specialists and consultant physicians to request the determination of HRD status in patients with newly diagnosed advanced or metastatic high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer.

Item 73307 is applicable once per primary tumour diagnosis and includes a service described in item 73301.

For private health insurance purposes, item 73307 will 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?

HRD testing will identify an additional subgroup of patients who may benefit from or are likely to respond to treatments with PARP inhibitor therapies listed under the PBS. A positive homologous recombination deficiency status (in the absence of a pathogenic *BRCA1* or *BRCA2* variant) would support access to PARP inhibitors listed under the PBS.

At its March 2023 meeting, the Medical Services Advisory Committee (MSAC) supported the creation of a new MBS item to test tumour tissue for genomic instability to determine HRD status (including *BRCA1/2* status) to determine eligibility for treatment with a PARP inhibitor, under Application 1658.1. MSAC supported this testing in patients with advanced, high grade serous or other non-mucinous high grade ovarian, fallopian tube or primary peritoneal carcinoma. Further details about MSAC applications can be found under MSAC Applications on the MSAC website (Medical Services Advisory Committee).

At its July 2023 meeting, the Pharmaceutical Benefits Advisory Committee (PBAC) supported the expansion of the listing for Olaparib, a PARP inhibitor, on the PBS for use in combination with bevacizumab for maintenance therapy in patients with newly diagnosed HRD positive *BRCA* wild type advanced epithelial ovarian, fallopian tube or primary peritoneal carcinoma.

What does this mean for requesters and providers?

From 1 January 2024, specialists and consultant physicians will be able to request MBS funded testing to determine HRD status (including *BRCA1* and *BRCA2* status) in tumour tissue from patients with newly diagnosed advanced or metastatic high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer.

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 newly diagnosed advanced or metastatic ovarian, fallopian tube or primary peritoneal 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 Australian Pathology, Public Pathology Australia, the Royal College of Pathologists of Australasia, Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Queensland Cancer Clinical Network and Queensland Cancer Genomics Steering Committee, Australian Genomics, Australian Genomic Cancer

Medicine Centre, Myriad Genetics and Ovarian Cancer Australia 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 January 2024)

Category 6 – Pathology Services

Group P7 - Genetics

73307

A test of tumour tissue from a patient with advanced (FIGO III-IV), high-grade serous or other high-grade ovarian, fallopian tube or primary peritoneal carcinoma, requested by a specialist or consultant physician, if the test is:

(a) to determine eligibility with respect to homologous recombination deficiency (HRD) status, including *BRCA1* or *BRCA2* status, to provide access to poly (adenosine diphosphate [ADP]-ribose) polymerase (PARP) inhibitor therapy under the Pharmaceutical Benefits Scheme; and

(b) including a service described in item 73301

Applicable once per primary tumour diagnosis

MBS Fee: $3,000.00

Benefit: 75% = $2,250.00 **85% = $2,901.30**

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.