Genetic testing for BRCA1/2 gene variants for patients with metastatic castration-resistant prostate cancer

Last updated: 29 March 2022

- From 1 April 2022, patients with metastatic castration-resistant prostate cancer (mCRPC) will be able to access MBS funded genetic testing to detect both somatic and/or germline BRCA1 or BRCA2 gene variants, to determine eligibility for the Pharmaceutical Benefits Schedule (PBS) listed drug Lynparza® (olaparib).

What are the changes?

From 1 April 2022, two new genetic testing items will be introduced to the Medicare Benefits Schedule (MBS) to determine eligibility for access to PBS-funded olaparib in patients with mCRPC:

- new MBS item 73303 will enable testing for BRCA gene variants in tumour tissue samples from patients with mCRPC; and
- new MBS item 73304 will enable testing for germline BRCA gene variants in patients with mCRPC for whom tumour testing is not possible.

Why are the changes being made?

In November 2021, the Pharmaceutical Benefits Advisory Committee (PBAC) recommended the PBS listing of olaparib for this patient population. Following this decision, the Medical Services Advisory Committee (MSAC) supported an application to list two new items to introduce testing for somatic and germline BRCA1 and BRCA2 gene variants in patients with mCRPC.

How will these changes affect patients?

The listing of these new items will mean that a patient with mCRPC can be tested for pathogenic or likely pathogenic BRCA1 and BRCA2 gene variants, to determine eligibility for clinically appropriate access to treatment with PBS listed olaparib.

What does this mean for providers/referrers/other stakeholders?

Providers will be able to request MBS funded testing to detect pathogenic or likely pathogenic BRCA gene variants in the tumour tissue (somatic testing) of patients with mCRPC. A second item can also be requested for germline testing to detect pathogenic or likely pathogenic BRCA gene variants in this patient population, should somatic testing of tissue samples not be pursued.

Who was consulted on the changes?

Consultation has been undertaken with key stakeholders, clinical experts and providers, and consumer health representatives as part of the MSAC and PBAC processes.

How will the changes be monitored and reviewed?

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

Significant variation from forecasted expenditure may warrant review and amendment of fees, and incorrect use of MBS items can result in penalties including the health professional being asked to repay monies that have been incorrectly received.

MBS pathology items will be reviewed by MSAC approximately 24 months post-implementation

Where can I find more information?

If you have a query relating to the interpretation of the MBS, you should email AskMBS. Subscribe to 'News for Health Professionals' on the Services Australia website to receive regular news highlights.

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

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