Changes to MBS item 73295 and two new MBS items (73301 and 73302) for patients with relapsed ovarian fallopian tube or primary peritoneal cancer to determine access to olaparib

- From 1 August 2020, patients with epithelial ovarian, fallopian tube or primary peritoneal cancer will be able to access MBS funded testing to detect both somatic and germline *BRCA1* or *BRCA2* gene variants, to determine eligibility for the Pharmaceutical Benefits Schedule (PBS) listed drug Lynparza® (olaparib).
- The new MBS item 73301 will enable testing for somatic *BRCA* gene variants in tumour samples from patients with these cancers, enabling access for eligible patients to olaparib if their first treatment was ineffective or is no longer working. Access to olaparib may assist patients with ovarian fallopian tube or primary peritoneal cancer and a *BRCA* mutation, without having to know whether this mutation was inherited or is present only in the tumour.
- Amendment to MBS item 73295 and the creation of 73302 will support germline *BRCA* testing for this patient group.
- The addition of two new MBS items 73301 and 73302 will co-incide with changes to the PBS to make olaparib available to the same eligible patient population (commencing 1 August 2020).

What are the changes?

- New item 73301 will be introduced for testing of the tumour tissue (somatic testing) to detect *BRCA1* or *BRCA2* pathogenic or likely pathogenic gene variants, in a patient with advanced (FIGO stage III-IV) high-grade ovarian epithelial, fallopian tube or primary peritoneal cancer. These tests are to determine the eligibility of patients for PBS listed olaparib.
- MBS item 73295 will be amended to align with new MBS item 73301, using updated terminology such as ‘pathogenic or likely pathogenic gene variants’ to reflect current clinical terminology.
- New item 73302 will be introduced to determine whether the presence of somatic *BRCA* markers detected by item 73301, are the result of a hereditary (‘germline’) pathogenic or likely pathogenic *BRCA1* or *BRCA2* gene variant. This will further inform the clinician who may recommend testing of the patient’s family members based on the test result.

Why are the changes being made?

The Pharmaceutical Benefits Advisory Committee (PBAC) recommended PBS listing of olaparib for this patient population (commencing from 1 August 2020). The Medical Services Advisory Committee (MSAC) supported an

application to amend MBS item 73295 and to include two new items to expand access to olaparib for patients with advanced (FIGO stage III-IV) high-grade ovarian epithelial, fallopian tube or primary peritoneal cancer, who have *BRCA* variants detected, regardless of whether the *BRCA* variants are the result of germline variant/s or not, and to introduce testing for somatic *BRCA1* and *BRCA2* gene variants in tumour material.

How will these changes affect patients?

Patients with epithelial ovarian, fallopian tube or primary peritoneal cancer will be able to access MBS funded testing to detect both somatic (MBS Item 73301) and germline (MBS item 73295) *BRCA1* or *BRCA2* gene variants, to determine eligibility to access olaparib as a second-line treatment. Eligibility for olaparib was previously limited to patients with germline *BRCA* variants only.

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 epithelial ovarian, fallopian tube or primary peritoneal cancer. This testing and subsequent access to olaparib was previously limited to patients with germline (hereditary) BRCA gene variants only.

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?

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 provides an email advice service for providers seeking advice on interpretation of the MBS items and rules and the Health Insurance Act and associated regulations. If you have a query relating exclusively to interpretation of the Schedule, you should email askMBS@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 is expected to become available on [date] and can be accessed via the MBS Online website under the Downloads page.

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