Addition of entrectinib to MBS item 73344 for fluorescent in situ hybridisation (FISH) testing for ROS proto-oncogene 1 (ROS1) rearrangements in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC)

- From 1 August 2020, Medicare Benefits Schedule (MBS) item 73344 for FISH testing for *ROS1* gene rearrangements in patients with locally advanced or metastatic NSCLC, is changing to to enable testing to determine eligibility for entrectinib.
- This change to MBS item 73344 will co-incide with changes to the Pharmaceutical Benefits Scheme (PBS) to make entrectinib available to the same eligible patient population (commencing 1 August 2020).
- There will be no change to the schedule fee for MBS item 73344.

What are the changes?

MBS item 73344 is being amended so that a service can be claimed for ROS1 gene rearrangement testing for NSCLC patients to determine eligibility for PBS listed entrectinib. Item 73344 already provides for testing to determine access to the PBS listed drug crizotinib.

Why are the changes being made?

The Pharmaceutical Benefits Advisory Committee (PBAC) recommended PBS listing of entrectinib for this patient population (this is commencing from 1 August 2020).The Medical Services Advisory Committee (MSAC) subsequently supported an application to amend MBS item 73344 to extend ROS1 gene rearrangement testing to help determine patient access to PBS-subsidised entrectinib. MSAC previously advised that ROS1 gene rearrangement testing is safe, clinically effective and cost-effective in patients with NSCLC. The Australian Government has approved these changes.

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

The addition of entrectinib to MBS item 73344 will provide an MBS funded service to assist providers in determining the eligibility of their patient for an additional PBS listed treatment option, entrectinib.

How will these changes affect patients?

The addition of entrectinib to MBS item 73344 will allow MBS funding for a test to determine the eligibility of NSCLC patients for an additional PBS listed treatment, entrectinib.

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.