Australian Government
Department of Health and Aged Care

Genetic testing changes for Pharmaceutical Benefits Scheme (PBS) immunotherapy

Last updated: 20 October 2022

What are the changes?

From 1 November 2022, pathology Medicare Benefits Schedule (MBS) items 73337, 73341 and 73344 will be amended to replace the reference to the specific drug 'pembrolizumab' with a general reference to 'immunotherapy'.

For private health insurance purposes, MBS items 73337, 73341 and 73344 will continue to be listed under the following clinical category and procedure type:

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

Why are the changes being made?

At its November 2021 meeting, the Pharmaceutical Benefits Advisory Committee (PBAC) supported the listing of cemiplimab on the Pharmaceutical Benefits Scheme (PBS) to treat patients with previously untreated metastatic non-small cell lung cancer (NSCLC). Further information regarding the PBAC decision can be found in the PBAC Public Summary Document (PSD) under PBAC item 5.06.

As part of its decision, PBAC recommended that cemiplimab should only be used for patients with a programmed cell death ligand 1 (PD-L1) tumour proportion score ≥50% with no evidence of an activating epidermal growth factor receptor (EGFR) gene, an anaplastic lymphoma kinase (ALK) gene rearrangement or a ROS proto-oncogene 1 (ROS1) gene arrangement in tumour materials.

At its November 2021 meeting, the Medical Services Advisory Committee (MSAC) supported amendments to MBS items 73337, 73341 and 73344 to enable Medicare benefits to be payable for biomarker testing to determine if the PBS requirements for cemiplimab relating to EGFR, ALK or ROS1 gene status are met. MSAC also supported the term 'immunotherapy' to replace 'pembrolizumab' in the MBS items 73337, 73341 and 73344 to cover both pembrolizumab and cemiplimab. Testing to determine PDL-1 status may be performed under MBS item 72814.

Further information about the MSAC decision can be found in the MSAC PSD under MSAC application 1642.

What does this mean for referrers and providers?

Medicare funded biomarker testing as described in MBS items 73337, 73341 and 73344 may be requested by a specialist or consultant physician to determine if requirements relating to EGFR, ALK or ROS1 gen status for access to cemiplimab or pembrolizumab under the PBS are fulfilled.

How will these changes affect patients?

Eligible patients will have access to Medicare funded biomarker testing to determine if requirements related to EGFR, ALK or ROS1 for access to an immunotherapy, such as cemiplimab or pembrolizumab, under the PBS are fulfilled.

Immunotherapy drugs, such as pembrolizumab and cemiplimab, are drugs that are used to treat a number of cancers.

Who was consulted on the changes?

MSAC reviews new or existing medical services or technology, and the circumstances under which public funding should be supported through listing on the MBS. This includes the listing of new items, or amendments to existing items on the MBS.

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 current item descriptors and information on other changes to the MBS can be found on the MBS Online website at www.mbsonline.gov.au with these amendments becoming available on 1 November 2022. 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, please 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 when available can be accessed via 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.

Amended MBS item descriptors (effective from 1 November 2022)

Item: 73337

Amended item descriptor: A test of tumour tissue from a patient diagnosed with non-small cell lung cancer, shown to have non-squamous histology or histology not otherwise specified, requested by, or on behalf of, a specialist or consultant physician, to determine:

(a) if the requirements relating to epidermal growth factor receptor (EGFR) gene status for access to an EGFR tyrosine kinase inhibitor under the Pharmaceutical Benefits Scheme are fulfilled; or

(b) if the requirements relating to EGFR status for access to ~~**pembrolizumab**~~ **an immunotherapy listed** under the Pharmaceutical Benefits Scheme are fulfilled.

Fee: $397.35 **Benefit**: **75%** = $298.05 **85%** = $337.75

Item: 73341

Amended item descriptor: Fluorescence in situ hybridisation (FISH) test of tumour tissue from a patient with locally advanced or metastatic non-small cell lung cancer, which is of non-squamous histology or histology not otherwise specified, with documented evidence of anaplastic lymphoma kinase (ALK) immunoreactivity by immunohistochemical (IHC) examination giving a staining intensity score > 0, and with documented absence of activating mutations of the epidermal growth factor receptor (EGFR) gene, requested by a specialist or consultant physician, to determine:

(a) if requirements relating to ALK gene rearrangement status for access to an anaplastic lymphoma kinase inhibitor under the Pharmaceutical Benefits Scheme are fulfilled; or

(b) if requirements relating to ALK status for access to ~~**pembrolizumab**~~ **an immunotherapy listed** under the Pharmaceutical Benefits Scheme are fulfilled.

Fee: $400.00 **Benefit**: **75%** = $$300.00 **85%** = $340.00

Item: 73344

Amended item descriptor: Fluorescence in situ hybridization (FISH) test of tumour tissue from a patient with locally advanced or metastatic non-small-cell lung cancer, which is of non-squamous histology or histology not otherwise specified, with documented evidence of ROS proto-oncogene 1 (ROS1) immunoreactivity by immunohistochemical (IHC) examination giving a staining intensity score of 2+ or 3+; and with documented absence of both activating mutations of the epidermal growth factor receptor (EGFR) gene and anaplastic lymphoma kinase (ALK) immunoreactivity by IHC, requested by a specialist or consultant physician, to determine:

(a) if requirements relating to ROS1 gene arrangement status for access to crizotinib or entrectinib under the Pharmaceutical Benefits Scheme are fulfilled; or

(b) if requirements relating to ROS1 status for access to ~~**pembrolizumab**~~ **an immunotherapy listed** under the Pharmaceutical Benefits Scheme are fulfilled.

Fee: $400.00 **Benefit**: **75%** = $300.00 **85%** = $340.00