Small Gene Panel Testing for Non-Small Cell Lung Carcinoma (NSCLC)

Last updated: 22 November 2023

- On 1 November 2023, three new pathology items were listed on the Medicare Benefits Schedule (MBS) for the detection of biomarkers in patients with NSCLC (of non-squamous histology or histology not otherwise specified), using small gene panels.
- On 1 November 2023, four existing pathology items on the MBS that are used to test for single biomarkers associated with NSCLC, were amended to account for the new gene panel items.
- This will result in better health outcomes for patients, including longer survival, and allow patients who test positive for certain biomarkers to access targeted treatments through the Pharmaceutical Benefits Scheme (PBS).

What are the changes?

Effective 1 November 2023, three new pathology items will be listed on the MBS for the detection of variants in epidermal growth factor receptor (*EGFR*), proto-oncogene B-Raf (*BRAF*), KRAS proto-oncogene (*KRAS*) and *MET* proto-oncogene, MET receptor tyrosine kinase exon 14 (*MET* exon 14) and the fusion status of at least anaplastic lymphoma kinase (*ALK*), ROS proto-oncogene 1 (*ROS1*), RET proto-oncogene (*RET*), neurotrophic tropomyosin-receptor kinase 1 (*NTRK1*), neurotrophic tropomyosin-receptor kinase 2 (*NTRK2*) and neurotrophic tropomyosin-receptor kinase 3 (*NTRK3*), in patients with NSCLC (of non-squamous histology or histology not otherwise specified), using small gene panels. **Attachment A** to this factsheet lists the new and amended items.

One item will be for simultaneous DNA and RNA testing, while the other two are for sequential testing using either DNA (for variants) or RNA (for fusion status).

NSCLC is the most common type of lung cancer and is a heterogeneous disease with a range of genomic subtypes. These mutations and abnormal gene expressions drive the growth of cancer cells. Treatments are becoming increasingly available which target specific mutations and limit tumour growth. Patients on these treatments can experience benefits such as milder side effects from their cancer treatment or living for longer.

For NSCLC, the most common, harmful gene variants are in the *EGFR*, *ALK*, *ROS1* and *MET* genes. Currently, people with NSCLC are tested for these gene variants sequentially – that is, one test after another. The new MBS items are for gene panel testing, meaning the laboratory can test for all (or a group of) these gene variants at once. The gene panel approach means that testing doesn't use as much tumour tissue to get a result and multiple results can be provided at the same time from the same tumour sample.

For private health insurance purposes, the new items have been listed under the following clinical category and procedure type:

- New items 73437, 73438, 73439 and amended items 73337, 73341, 73344 and 73436:
    - Clinical category: Support List (pathology)
    - Procedure type: Type C

Why are the changes being made?

The listing of this service was recommended by the Medical Services Advisory Committee (MSAC) in November 2022 under MSAC Application 1721. Further details about MSAC applications can be found under MSAC Applications on the MSAC website (Medical Services Advisory Committee).

Overall, MSAC supported the listing of the proposed MBS items because the evidence for gene panel testing demonstrated superior effectiveness owing to its improved test success rate (i.e., more samples with sufficient quantity and/or quality to be able to be successfully tested for variants), improved variant detection rate and superior safety due to the reduced need for re-biopsy compared with sequential single gene tests with acceptable cost effectiveness and financial implications.

What does this mean for requestors and providers?

From 1 November 2023, specialists or consultant physicians have been able to order gene panel testing for patients who are newly diagnosed with NSCLC, in order to determine eligibility for targeted treatments listed on the Pharmaceutical Benefits Scheme (PBS).

Using a gene panel makes better use of the tumour tissue available for testing, making it safer (as less biopsies are needed) as well as potentially cheaper and faster than testing one gene at a time.

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 test on the MBS means patients who are newly diagnosed with NSCLC, will have timely access to treatment that is clinically appropriate and reflects modern clinical practice – providing an opportunity for better health outcomes including longer survival.

Who was consulted on the changes?

Consultation feedback was received from Australian Genomics, Human Genetics Society of Australasia (HGSA), InGeNa, Public Pathology Australia (PPA) and the Thoracic Oncology Group of Australasia (TOGA), Jansen-Cilag, Roche Products Pty Ltd and Roche Diagnostics Australia (Roche), Public Pathology Australia and Australian Pathology. The application for these new items (MSAC Application 1721) was submitted by the Royal College of Pathologists of Australasia.

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 descriptors (commenced 1 November 2023)

Category 6 – Pathology Services

Group P7 – Genetics

73437

A nucleic acid-based multi-gene panel test of tumour tissue from a patient with a new diagnosis of non-small cell lung cancer requested by, or on behalf of, a specialist or consultant physician, if the test is:

(a) to detect variants in at least *EGFR*, *BRAF*, *KRAS* and *MET* exon 14 to determine access to specific therapies relevant to these variants listed on the Pharmaceutical Benefits Scheme (PBS); and

(b) to detect the fusion status of at least *ALK*, *ROS1*, *RET*, *NTRK1*, *NTRK2* and *NTRK3*; and

(i) to determine access to specific therapies relevant to these variants listed on the PBS; or

(ii) determine if the requirements relating to *EGFR*, *ALK* and *ROS1* status for access immunotherapies listed on the PBS are fulfilled; and

(c) not associated with a service to which item 73438, 73439, 73337, 73341, 73344, 73436 or 73351 applies

MBS Fee: $1,247.00

Benefit: 75% = $935.25 85% = $1,148.30 (Greatest Permissible Gap (GPG) will apply)

Category 6 – Pathology Services

Group P7 – Genetics

73438

A DNA-based multi-gene panel test of tumour tissue from a patient with a new diagnosis of non-small cell lung cancer requested by, or on behalf of, a specialist or consultant physician, if the test is:

(a) to detect variants in at least *EGFR*, *BRAF*, *KRAS* and *MET* exon 14; and

(b) to determine access to specific therapies relevant to these variants listed on the Pharmaceutical Benefits Scheme (PBS); or

(c) to determine if the requirements relating to EGFR status for access to immunotherapies listed on the PBS are fulfilled; and

(d) not associated with a service to which item 73437, 73337, 73436 or 73351 applies

MBS Fee: $682.35

Benefit: 75% = $511.80 85% = $583.65 (Greatest Permissible Gap (GPG) will apply)

Category 6 – Pathology Services

Group P7 – Genetics

73439

A nucleic acid-based multi-gene panel test of tumour tissue from a patient with a new diagnosis of non-small cell lung cancer and with documented absence of activating variants of the *EGFR* gene, *KRAS*, *BRAF* and *MET* exon14, requested by, or on behalf of, a specialist or consultant physician, if the test is:

(a) to determine the fusion status of at least *ALK*, *ROS1*, *RET*, *NTRK1*, *NTRK2*, and *NTRK3* to determine access to specific therapies relevant to these variants listed on the Pharmaceutical Benefits Scheme (PBS) are fulfilled; or

(b) to determine if the requirements relating to *ALK* and *ROS1* status for access to immunotherapies listed on the PBS are fulfilled; and

(c) not associated with a service to which item 73437, 73341, 73344 or 73351 applies

MBS Fee: $682.35

Benefit: 75% = $511.80 85% = 583.65 (Greatest Permissible Gap (GPG) will apply)

Amended item descriptors (commenced 1 November 2023)

Category 6 – Pathology Services

Group P7 – Genetics

73337

A test of tumour tissue from a patient with a new diagnosis of 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, if the test is:

(a) to determine if requirements relating to epidermal growth factor receptor (*EGFR*) gene status for access to an immunotherapy listed under the Pharmaceutical Benefits Scheme (PBS) are fulfilled; and
(b) not associated with a service to which item 73437 or 73438 applies

MBS Fee: $397.35

Benefit: 75% = $298.05 85% = $337.75

Category 6 – Pathology Services

Group P7 – Genetics

73341

Fluorescence in situ hybridisation (FISH) test of tumour tissue from a patient with a new diagnosis of 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, if the test is:

(a) to determine if requirements relating to *ALK* gene rearrangement status for access to an immunotherapy listed under the Pharmaceutical Benefits Scheme (PBS) are fulfilled; and
(b) not associated with a service to which item 73437 or 73439 applies

MBS Fee: $400.00

Benefit: 75% = $300.00 85% = $340.00

Category 6 – Pathology Services

Group P7 – Genetics

73344

Fluorescence in situ hybridization (FISH) test of tumour tissue from a patient with a new diagnosis of 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, if the test is:

(a) to determine if requirements relating to *ROS1* gene arrangement status for access to an immunotherapy listed under the Pharmaceutical Benefits Scheme (PBS) are fulfilled: and

(b) not associated with a service to which item 73437 or 73439 applies

MBS Fee: $400.00

Benefit: 75% = $300.00 85% = $340.00

Category 6 – Pathology Services

Group P7 – Genetics

73436

A test of tumour tissue from a patient with a new diagnosis of locally advanced or metastatic non-small cell lung cancer requested by, or on behalf of, a specialist or consultant physician, if the test is:

(a) to determine if the requirements relating to *MET* proto-oncogene, receptor tyrosine kinase (*MET*) exon 14 skipping alterations (*MET*ex14sk) status for access to an immunotherapy listed under the Pharmaceutical Benefits Scheme (PBS) are fulfilled: and

(b) not associated with a service to which item 73437 or 73438 applies

MBS Fee: $397.35

Benefit: 75% = $298.05 85% = $337.75

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.