Genetic testing for variants associated with haematological malignancies

Last updated: 22 November 2023

- From 1 November 2023, four new pathology items were listed on the Medicare Benefits Schedule (MBS) for next-generation sequencing (NGS) gene panel testing for genetic variants associated with haematological malignancies.
- This means better health outcomes for patients, by supporting clinicians to determine the specific type of blood cancer a patient has. This information can inform treatment options for that patient, help doctors understand what the patient's chances of recovery might be and whether the cancer might come back again.

What are the changes?

Effective 1 November 2023, four new pathology items were listed on the MBS, for NGS panel testing for genetic variants associated with haematological malignancies. **Attachment A** to this factsheet lists the new items.

Haematological malignancies (blood cancers) are a diverse group of diseases, and include cancers such as lymphoma, myeloma and leukaemia. They can be broadly categorised based on their cell of origin into myeloid or lymphoid cancers. Myeloid cancers are due to cancers in cells that come from the bone marrow. These cells ordinarily turn into red blood cells, platelets and some white blood cells. Lymphoid cancers are due to cancers in cells that come from the lymphatic system. These cells ordinarily turn into white blood cells that fight infections.

There are currently gene tests that look for variants in only a single gene for some blood cancers, available on the MBS. The proposed gene panels will include more genes than what is currently available. Using gene panels therefore increases the chance of finding relevant genetic variants and being able to make an accurate diagnosis. The World Health Organization recommends using genetic testing to accurately diagnose haematological malignancies.

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

- New items 73445, 73446, 73447 and 73448:
    - Clinical category: Support List (pathology)
    - Procedure type: Type C

Why are the changes being made?

NGS gene panel testing can provide diagnostic, prognostic and predictive information for patients with clinically suspected myeloid or lymphoid neoplasm where accurate diagnosis sufficient for treatment planning is not achieved using conventional testing. NGS testing means the laboratory can test for all (or a group of) these gene variants at once.

Testing covers a very broad range of conditions – for some, NGS gene panel testing is essential at diagnosis and has been the standard of care for more than 5000 Australians (e.g. myeloid malignancies, chronic lymphocytic leukaemia to test for clinically significant TP53 variants) – whereas, for other conditions, testing may be reserved for when all treatment avenues have been exploited (e.g. relapsed and refractory diffuse large B cell lymphoma) or those cases where a diagnosis cannot be made (e.g. lymphadenopathy of uncertain aetiology).

The listing of this service was recommended by the Medical Services Advisory Committee (MSAC) in November 2022 in response to MSAC Application 1684. Further details about MSAC applications can be found under MSAC Applications on the MSAC website (Medical Services Advisory Committee).

What does this mean for requestors and providers?

Specialists or consultant physicians are now able to request NGS gene panel testing for genetic variants associated with haematological malignancies. The MBS items is specifically for suspected malignancies of either myeloid or lymphoid origin. The MBS items also specify testing methodology using 1) DNA and RNA, and 2) DNA only, to reflect laboratories different testing capabilities.

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?

For patients with clinical or laboratory evidence of a suspected haematological malignancy, a NGS gene panel test during the initial work-up or at suspected disease progression/relapse will assist diagnosis and/or management. Patients will then have access to treatment that is clinically appropriate and reflects modern clinical practice – which will lead to better health outcomes.

Who was consulted on the changes?

The Department received responses from five organisations (Public Pathology Australia, Australian Genomics, Myeloproliferative Neoplasm Alliance Australia, Leukaemia Foundation and Australian Pathology), all of whom were supportive of the new services.

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
73445 Characterisation of a variant or variants in a panel of at least 25 genes using DNA and RNA, requested by a specialist or consultant physician, to determine the diagnosis, prognosis and/or management of a patient presenting with a clinically suspected haematological malignancy of myeloid origin Applicable once per diagnostic episode, at diagnosis, disease progression or relapse MBS Fee: $1,100.00 Benefit: 75% = $825.00 85% = $1,001.30 (Greatest Permissible Gap (GPG) will apply)

Category 6 – Pathology Services
Group P7 – Genetics
73446 Characterisation of a variant or variants in a panel of at least 25 genes using DNA and RNA, requested by a specialist or consultant physician, to determine the diagnosis, prognosis and/or management of a patient presenting with a clinically suspected haematological malignancy of lymphoid origin Applicable once per diagnostic episode, at diagnosis, disease progression or relapse MBS Fee: $1,100.00 Benefit: 75% = $825.00 85% = $1,001.30 (Greatest Permissible Gap (GPG) will apply)

Category 6 – Pathology Services
Group P7 – Genetics
73447

Category 6 – Pathology Services

Characterisation of a variant or variants in a panel of at least 25 genes using DNA, requested by a specialist or consultant physician, to determine the diagnosis, prognosis and/or management of a patient presenting with a clinically suspected haematological malignancy of myeloid origin

Applicable once per diagnostic episode, at diagnosis, disease progression or relapse

MBS Fee: $927.90

Benefit: 75% = $695.95 85% = $829.20 (Greatest Permissible Gap (GPG) will apply)

Category 6 – Pathology Services

Group P7 – Genetics

73448

Characterisation of a variant or variants in a panel of at least 25 genes using DNA, requested by a specialist or consultant physician, to determine the diagnosis, prognosis and/or management of a patient presenting with a clinically suspected haematological malignancy of lymphoid origin

Applicable once per diagnostic episode, at diagnosis, disease progression or relapse

MBS Fee: $927.90

Benefit: 75% = $695.95 85% = $829.20 (Greatest Permissible Gap (GPG) will apply)

PN.7.14

To apply to 73445, 73446, 73447 and 73448

Testing should include, but not be restricted to, genes described in the current World Health Organization Classification of Haematolymphoid Tumours: Lymphoid Neoplasms or other appropriate international guidelines.

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.