



# Detection of measurable residual disease (MRD) using a quantitative patient-specific molecular assay for patients with acute lymphoblastic leukaemia (ALL)

Last updated: 31 May 2024

- From 1 July 2024, two new pathology items will be listed on the Medicare Benefits Schedule (MBS) for the detection of MRD in patients with ALL, using a patient-specific molecular assay.
- This will result in better health outcomes for patients by allowing access to publicly funding testing to inform clinical decisions and determine suitability for Pharmaceutical Benefits Scheme (PBS) listed treatments.

## What are the changes?

Effective 1 July 2024, two new pathology items will be listed on the MBS for patients with ALL, for the development and subsequent use of patient-specific quantitative molecular assays to detect MRD.

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

- New items 73313 and 73316:
  - Clinical category: Support List (pathology)
  - Procedure type: Type B

## Why are the changes being made?

MRD testing is useful in providing diagnostic, prognostic and predictive information for patients with ALL and is the established standard of care for these patients.

ALL is a type of blood cancer that occurs when a genetic variant arises in a person's white blood cells and makes the cells multiply more than they should. Patients get treatment to try and kill the cancer cells, then tests are done to check how well treatment has worked. These tests either look for cells with the specific genetic variant that is causing the cancer in that patient or look at a range of genetic variants that can cause ALL.

When a patient has MRD, they have a small number of cancer cells that cannot be seen with a microscope but can be detected using genetic tests. Detecting MRD means a patient's

cancer is more likely to return (known as relapse), and patients and clinicians can use this information to change the patient's management. For example, testing may inform a patient's treatment with drugs available through the PBS.

The listing of this service was recommended by the Medical Services Advisory Committee (MSAC) in March 2023 when considering [MSAC Application 1703](#). More information about the MSAC Executive is available in [MSAC Executive Terms of Reference](#) in the Department of Health and Aged Care website ([Department of Health and Aged Care website](#)).

## What does this mean for requestors and providers?

Specialists or consultant physicians practising as haematologists or oncologists will be able to request MRD testing for patients with ALL in order to provide more targeted treatment where necessary, including access to the drug blinatumomab.

There are several scientific methods that can be used to test for measurable residual disease in a laboratory, including multiparametric flow cytometry (mpFC), next-generation sequencing (NGS) and quantitative polymerase chain reaction (qPCR). Measuring MRD using qPCR requires the laboratory to develop a patient-specific assay for the genetic variant that is causing each patient's ALL.

Not all types of cancer-causing genetic variants can be detected using current testing methods. One MRD testing method will not work for all patients. Different MRD testing method options need to be available. Items for MRD testing using mpFC (item 71202) and NGS methods (73310), were listed on the MBS on 1 November 2023.

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 these new items on the MBS means every patient with ALL will have access to testing to inform treatment that is clinically appropriate and reflects modern clinical practice – leading to better health outcomes.

## Who was consulted on the changes?

Both targeted and open public consultation was undertaken by the Department of Health and Aged Care on behalf of MSAC. Feedback was received from Adaptive Biotechnologies, the Australia and New Zealand's Children's Haematology Oncology Group, Australian Leukaemia and Lymphoma Group, Australian Pathology, the Haematology Society of Australia and New Zealand, the Leukaemia Foundation, PathWest laboratory WA (PathWest), the Prince of Wales Hospital (Sydney) and one individual who was a hospital-based specialist in this area of medicine.

## 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.

Providers are responsible for ensuring services claimed from Medicare using their provider number meet all legislative requirements. These changes are subject to MBS compliance checks and providers may be required 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](http://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](mailto:askMBS@health.gov.au).

Private health insurance information on the product tier arrangements is available at [www.privatehealth.gov.au](http://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](mailto: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.

## New item descriptors (to take effect 1 July 2024)

### Category 6 – Pathology Services

#### Group P7 - Genetics

##### 73313

**Development of a quantitative patient-specific molecular assay for measurable residual disease (MRD) testing performed on bone marrow (or a peripheral blood sample if bone marrow cannot be collected) from a patient diagnosed with acute lymphoblastic leukaemia treated with combination chemotherapy or after salvage therapy, including the first service described in item 73316 performed on that bone marrow or peripheral blood sample, requested by a specialist or consultant physician practising as a haematologist or oncologist**

Applicable once per patient per episode of disease or per relapse

(See para PN.7.20 of explanatory notes to this Category)

MBS Fee: \$3,000.00

Benefit: 75% = \$2,250.00    85% = \$2,451.30 (Greatest Permissible Gap will apply)

### Category 6 – Pathology Services

#### Group P7 - Genetics

##### 73316

Measurable residual disease (MRD) testing by a quantitative patient-specific molecular assay performed on bone marrow (or, in a patient with T-cell acute lymphoblastic leukaemia, performed on a peripheral blood sample if bone marrow cannot be collected) from a patient diagnosed with acute lymphoblastic leukaemia treated with combination chemotherapy or after salvage therapy, requested by a specialist or consultant physician practising as a haematologist or oncologist, other than a service associated with a service to which item 73313 applies

(See para PN.7.20 of explanatory notes to this Category)

MBS Fee: \$780.00

Benefit: 75% = \$585.00    85% = \$681.30 (Greatest Permissible Gap will apply)

## Category 6 – Pathology Services

### **PN.7.20**

The number of measurable residual disease (MRD) tests per patient, per episode of disease or per relapse is not expected to exceed 12, inclusive of a baseline assessment.

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.