

Detection of measurable residual disease (MRD) in patients with acute lymphoblastic leukaemia (ALL)

Last updated: 22 November 2023

- From 1 November 2023, two new pathology items were listed on the Medicare Benefits Schedule (MBS) for the detection of measurable residual disease (MRD) in patients with acute lymphoblastic leukaemia (ALL).
- This means better health outcomes for patients, including longer survival, and allows all
 patients who test positive for MRD to access the drug blinatumomab through the
 Pharmaceutical Benefits Scheme (PBS).

What are the changes?

Effective 1 November 2023, two new pathology items (71202 and 73310) were listed on the Medicare Benefits Schedule (MBS) for the detection of MRD in patients with ALL, using flow cytometry and next-generation sequencing (NGS) methods. **Attachment A** to this factsheet lists the new items.

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 to check how well it has worked there are tests that 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, this means 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 treatment. Testing allows patients to be eligible for more targeted treatment, including use of the drug blinatumomab which is accessible through the PBS.

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

- New items 71202 and 73310:
 - Clinical category: Support List (pathology)
 - o Procedure type: Type C

Why are the changes being made?

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

The listing of this service was recommended by the Medical Services Advisory Committee (MSAC) in November 2022. Further details about the MSAC application can be found under application 1707 in <u>MSAC Applications</u> on the MSAC website (<u>Medical Services Advisory Committee</u>).

What does this mean for requestors and providers?

Specialists or consultant physicians practising as a haematologist or oncologist are now able to request MRD testing for patients with ALL in order to provide more targeted treatment where necessary, including access to the drug blinatumomab.

To be eligible for Medicare benefits, laboratories providing this service must be accredited according to the pathology accreditation standards specified in the <u>Health Insurance</u> (Accredited Pathology Laboratories-Approval) Principles 2017.

How will these changes affect patients?

The listing of this test on the MBS means every patient with ALL now has access to treatment that is clinically appropriate and reflects modern clinical practice – which will lead to better health outcomes including longer survival.

Who was consulted on the changes?

Consultation was undertaken with Adaptive Biotechnologies, PathWest laboratory medicine WA (PathWest), Australian Pathology (AP) and one individual who was a researcher.

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 P4 - Immunology

71202

Measurable residual disease (MRD) testing by flow cytometry, performed on bone marrow from a patient diagnosed with acute lymphoblastic leukaemia, for the purpose of determining baseline MRD, or facilitating the determination of MRD following combination chemotherapy or after salvage therapy, requested by a specialist or consultant physician practising as a haematologist or oncologist.

MBS Fee: \$550.00

Benefit: 75% = \$412.50 85% = \$467.50

Category 6 - Pathology Services

Group P7 - Genetics

73310

Measurable residual disease (MRD) testing by next-generation sequencing, performed on bone marrow (or a peripheral blood sample if bone marrow cannot be collected) from a patient diagnosed with acute lymphoblastic leukaemia (ALL) for the purposes of determining baseline MRD or facilitating the determination of MRD following combination chemotherapy or after salvage therapy, requested by a specialist or consultant physician practising as a haematologist or oncologist.

MBS Fee: \$1,550.00

Benefit: 75% = \$1,162.50 85% = \$1,451.30 (Greatest Permissible Gap (GPG) will apply)

PN.0.35

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.