

17p chromosomal deletion testing for chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Last updated: 16 June 2023

- From 1 July 2023, one existing item on the Medicare Benefits Schedule (MBS) for 17p deletion testing for CLL or SLL will be amended to extend access to a wider range of patients.
- These changes are relevant for medical practitioners that specialise in or consult on CLL or SLL

What are the changes?

Effective 1 July 2023, existing MBS item 73343 will be amended to:

- Expand access to all patients who suffer from CLL or SLL. Previously, only patients with relapsed or refractory CLL or SLL had access to item 73343.
- Include lymph node samples as an appropriate sample type. Previously, only peripheral blood samples or bone marrow samples could be used.
- Remove the requirement for MBS item 73343 to be used to determine access to a Pharmaceutical Benefits Scheme (PBS) listed drug.
- Remove the frequency restriction limiting the item to not more than once in 12 months to allow patients to access the service when required, including at initial diagnosis, disease relapse, or disease progression when initiation of, or change of therapy is anticipated.

The amended MBS item descriptor is provided at <u>Attachment A</u>.

For private health insurance purposes, item 73343 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?

The changes were recommended by the Medical Services Advisory Committee (MSAC) at its November 2019 meeting under <u>MSAC application 1560 - 17p deletion testing by</u> fluorescence in situ hybridization for access to ibrutinib in patients with previously untreated chronic lymphoid leukaemia or small lymphocytic lymphoma and <u>MSAC application 1544 - Genome-wide microarray testing for people with multiple myeloma and chronic lymphocytic leukaemia and confirmed in detail by MSAC Executive at its August 2022 meeting.</u>

What does this mean for requestors and providers?

Specialists who manage patients with CLL or SLL will be able to request Medicare funded testing for 17p chromosomal deletion as needed, including at initial diagnosis; disease relapse; or disease progression when initiation of, or change in therapy is anticipated.

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 amendment of MBS item 73343 will provide greater access for patients to Medicare funded 17p chromosomal deletion.

Who was consulted on the changes?

Consultation has been undertaken with peak medical bodies including the Royal College of Pathologists of Australasia and the Haematological Society of Australia and New Zealand. The consulted stakeholders were supportive of the amendments to item 73343.

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 <u>www.mbsonline.gov.au.</u> You can also subscribe to future MBS updates by visiting <u>MBS Online</u> 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 <u>askMBS@health.gov.au</u>.

Private health insurance information on the product tier arrangements is available at <u>www.privatehealth.gov.au</u>. Detailed information on the MBS item listing within clinical categories is available on the <u>Department's website</u>. 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 <u>Federal Register of Legislation</u>. If you have a query in relation to private health insurance, you should email <u>PHI@health.gov.au</u>.

Subscribe to '<u>News for Health Professionals</u>' 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 <u>Downloads</u> page.

Attachment A: Amended item descriptor to take effect 1 July 2023 (deletions in red strike through, additions in red text)

Category 6 – Pathology Services

Group P7 - Genetics

73343

Detection of 17p chromosomal deletions by fluorescence in situ hybridisation or genome wide micro-array, in a patient with **relapsed or refractory** chronic lymphocytic leukaemia or small lymphocytic lymphoma, on a peripheral blood, or bone marrow **or lymph node** sample, requested by a specialist or consultant physician., to determine if the **requirements for access to idelalisib, ibrutinib, venetoclax or acalabrutinib on the Pharmaceutical Benefits Scheme are fulfilled**.

For any particular patient, at initial diagnosis, at disease relapse, or on disease progression only, where initiation of or change in therapy is anticipated, applicable not more than once in 12 months.

MBS Fee: \$589.90 Benefit: 75% = \$442.45 85% = \$501.45

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.