New Medicare Benefits Schedule (MBS) item for Fibroblast growth factor 23 (FGF-23) testing for patients with a high pre-test probability of X-linked hypophosphatemia (XLH) to determine eligibility for a relevant treatment on the Pharmaceutical Benefits Scheme (PBS)

Last updated: 15 October 2025

- From 1 November 2025, a new MBS item 66520 will be listed on the Medicare Benefits Schedule (MBS) for fibroblast growth factor receptor 23 (FGF-23) testing to determine patients' eligibility for a relevant treatment on the Pharmaceutical Benefits Scheme (PBS).
- The new item will support FGF-23 testing in patients with a high pre-test probability of X-linked hypophosphatemia (XLH), who are being considered for treatment using burosumab or other relevant treatment(s) that may become listed on the PBS.
- The new item is relevant for specialists and consultant physicians who manage patients with XLH.

What are the changes?

Effective 1 November 2025, a new MBS item 66520 will be listed for FGF-23 testing for patients with a high pre-test probability of XLH for the purpose of determining eligibility for treatment using burosumab or any other new relevant treatment(s) that may become listed on the PBS.

For private health insurance purposes, item 66520 will be listed under the following clinical category and procedure type:

Clinical category: Support List (Pathology)

Procedure type: Type C

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

Why are the changes being made?

Following recommendation by the PBAC, burosumab was listed on the PBS on 1 November 2022 for the treatment of patients with XLH. Some patients are accessing this treatment through a genetic test to detect a mutation in the PHEX (Phosphate Regulating Endopeptidase X-Linked) gene that is known to cause XLH.

In August 2024, to improve access to burosumab, MSAC supported application 1778 for listing of a new MBS item for FGF-23 testing to determine eligibility for access to a relevant treatment listed on the PBS. MSAC supported use of the words 'to determine eligibility for a relevant treatment listed on the Pharmaceutical Benefits Scheme' in the MBS item descriptor rather than specifying burosumab, as this allows the MBS item to be used to determine eligibility for future PBS treatments, where they require measurement of FGF-23.

This new test is in addition to existing tests on the MBS used to confirm diagnosis of XLH. Further details about this MSAC application can be found in the MSAC 1778 public summary document.

What does this mean for requesters?

This MBS item will allow specialists and consultant physicians to request FGF-23 testing of serum or plasma from patients with a high pre-test probability of XLH for the purpose of determining patient eligibility for burosumab listed on the PBS. This MBS item will also enable testing for any future relevant treatment(s) listed on the PBS which require evidence of FGF-23 levels.

How will these changes affect patients?

XLH is a rare inherited condition that affects a number of body systems, including the bones. Patients with XLH have abnormally high levels of the hormone FGF-23 in their bodies which lead to low levels of phosphate. Phosphate along with calcium is stored in bones to build and keep them strong. When there is not enough phosphate in the body, like in patients with XLH, the bones cannot mineralise properly, so they grow to be malformed, painful and break easily. Patients with this condition can have chronic pain and significant problems with muscle and joint function, limiting their mobility. There is currently no cure for XLH.

Patients who have a diagnosis of XLH are eligible to access burosumab, a medication for the treatment of XLH listed on the PBS. Treatment with burosumab is not a cure. It increases phosphate levels which improves bone mineralisation and reduces the severity of the condition in patients with XLH.

The diagnosis of XLH includes a number of steps, one of which is testing for high FGF-23 levels (or unusually normal FGF-23 levels in patients who have other symptoms of XLH).

From 1 November 2025, patients with XLH will be able to access a Medicare benefit to test for FGF-23 levels, to determine eligibility for treatment using burosumab and any future relevant PBS-listed treatments.

Who was consulted on the changes?

The organisations who submitted input were:

- Australian Pathology
- Public Pathology Australia
- The Australian and New Zealand Bone and Mineral Society (ANZBMS).

The consultation feedback received was supportive.

How will the changes be monitored and reviewed?

Providers are responsible for ensuring Medicare services claimed using their provider number meet all legislative requirements. All Medicare claiming is subject to compliance checks and providers may be required to submit evidence about the services they bill. More information about the Department of Health, Disability and Ageing (the department's) compliance program can be found on its website at Medicare compliance.

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. You can also subscribe to future MBS updates by visiting 'Subscribe to the MBS' on the MBS Online website.

Providers seeking advice on interpretation of MBS items, explanatory notes and associated legislation can use the department's email advice service by emailing 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 to 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 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 descriptor (to take effect 1 November 2025)

Category 6 - Pathology Services

Group P2 - Chemical

66520

Fibroblast growth factor 23 quantification in serum or plasma, requested by a specialist or consultant physician to determine eligibility for a relevant treatment listed on the Pharmaceutical Benefits Scheme

Fee: \$90.00 Benefit: 75% = \$67.50 85% = \$76.50

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.