New Medicare Benefits Schedule (MBS) item for dihydropyrimidine dehydrogenase (DPYD) genotyping to diagnose or predict fluoropyrimidine (FP)-induced toxicity

Last updated: 15 October 2025

- From 1 November 2025, one new item for dihydropyrimidine dehydrogenase (DPYD)
 genotyping to diagnose or predict fluoropyrimidine (FP)-induced toxicity will be listed on
 the Medicare Benefits Schedule (MBS).
- The new item will support testing in patients with solid tumours who are about to commence, are undergoing or had a treatment protocol that includes a FP-based treatment by the treating specialist or consultant physician.
- The new item is relevant for specialists and consultant physicians who manage these cancer patients.

What are the changes?

Effective 1 November 2025, one new MBS item (73322) for *dihydropyrimidine dehydrogenase* (*DPYD*) genotyping to diagnose or predict fluoropyrimidine (FP)-induced toxicity will be listed on the Medicare Benefits Schedule (MBS).

Patients with solid tumours who are about to commence, are undergoing or had a treatment protocol that includes an FP treatment will be able to access Medicare benefits for the test to diagnose or predict FP-induced toxicity.

This will subsequently enable clinicians to adjust a patient's FP treatment dose or select an alternative treatment.

Only specialists and consultant physicians will be able to request the new MBS item for their patients.

Item 73322 will be applicable once per lifetime.

For private health insurance purposes, item 73322 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, test providers must be accredited according to the pathology accreditation standards specified in the <u>Health Insurance</u> (Accredited Pathology Laboratories-Approval) Principles 2017.

Why are the changes being made?

The changes arise from recommendations of the Medical Services Advisory Committee under Application 1760.

At its November 2024 meeting, the Medical Services Advisory Committee (MSAC) supported MBS funding for *dihydropyrimidine dehydrogenase* (*DPYD*) genotyping to predict FP-induced toxicity in patients with solid tumours who are about to commence FP-based treatment, after its assessment of <u>Application 1760</u>. MSAC also supported expanding the proposed patient population to include patients who are currently undergoing or have previously received FP-based treatment, to diagnose or predict FP-induced toxicity.

MSAC supported *DPYD* genotyping to diagnose or predict FP-induced toxicity as it is safe, cost-effective and has a high clinical need due to the life-threatening consequences associated with FP-induced toxicity.

Further details about MSAC applications can be found under <u>MSAC Applications</u> on the <u>MSAC website</u>.

What does this mean for requesters?

From 1 November 2025, specialists and consultant physicians will be able to request *DPYD* genotyping for patients with solid tumours who are about to commence, are undergoing or had a treatment protocol that includes a FP treatment under MBS item 73322. All MBS funded testing is to be rendered by Approved Pathology Practitioners.

How will these changes affect patients?

Patients with solid tumours who are about to commence, are undergoing or had a treatment protocol that includes an FP treatment will be able to access Medicare benefits for the test to predict or diagnose FP-induced toxicity. The *DPYD* gene encodes the dihydropyrimidine dehydrogenase (DPD) enzyme, which is needed to break down FP and remove it from the body. Reduced DPD enzyme activity can lead to elevated levels of FP in the body, increasing the toxicity risk from FPs. As such, *DPYD* genotyping will enable clinicians to predict or diagnose FP-induced toxicity in many patients and subsequently adjust a patient's FP treatment dose or select an alternative treatment.

Who was consulted on the changes?

The following organisations provided input into the MSAC process:

- Australasian Gastro-Intestinal Trials Group (AGITG)
- Australian Genomics
- Australian Pathology

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- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Bowel Cancer Australia (BCA)
- Consumer Representatives from Melbourne Genomics Health Alliance
- National Pathology Accreditation Advisory Council (NPAAC)
- PathWest Laboratory Medicine, QEII Medical Centre, Nedlands
- Therapeutic Goods Administration (TGA)
- The Royal College of Pathologists of Australasia (RCPA)
- The Society of Hospital Pharmacists of Australia (SHPA)

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's (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 P7 – Genetics

73322

Genetic testing in the DPYD gene to diagnose or predict fluoropyrimidine-induced toxicity in a patient, if:

- (a) the service is requested by a specialist or consultant physician; and
- (b) the service is rendered before, during or after systemic administration of chemotherapy or radio-sensitisation, with a fluoropyrimidine, to the patient; and
- (c) genotyping is performed to detect DPYD variants linked to reduced or absent dihydropyrimidine dehydrogenase activity.

Applicable once per lifetime.

Fee: \$182.00 Benefit: 75% = \$136.50 85% = \$154.70

(See para PN.7.22 of explanatory notes to this Category)

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.