



New Medicare Benefits Schedule (MBS) item for *isocitrate dehydrogenase 1 (IDH1)* variant testing in patients with cholangiocarcinoma (CCA) to determine eligibility for a relevant treatment on the Pharmaceutical Benefits Scheme (PBS)

Last updated: 30 June 2025

- From 1 July 2025 a new MBS item will be introduced on the Pathology Services Table of the MBS. This item is for *IDH1* variant testing of tumour tissue, to determine eligibility for a relevant treatment under the PBS for patients with histologically confirmed CCA.
- All patients with histologically confirmed CCA who are being considered for a relevant PBS listed treatment will be eligible for *IDH1* variant testing under the new item, regardless of stage or subtype.

What are the changes?

CCA is also known as bile duct cancer. The bile ducts are a group of thin tubes starting inside the liver that carry bile from the liver and gallbladder into the intestine. CCA is a rare and aggressive form of cancer, with few treatment options available to these patients and survival after diagnosis is usually relatively short. Significant *IDH1* genetic variants occur in the cancer of around 10% of people with CCA. The presence of these *IDH1* variants in patients with CCA leads to increased levels of an oncometabolite (a compound that contributes to cancer cell growth) called D-2-hydroxyglutarate (D2-HG).

On 1 July 2025 a new MBS item (73319) will be listed for *IDH1* variant testing of tumour tissue from patients with CCA for the purpose of determining eligibility for treatment with ivosidenib. The item descriptor will refer to 'relevant treatment listed under the Pharmaceutical Benefits Scheme' instead of specifying the drug or drug class. This is to ensure that the new item can be used to determine eligibility for any future, relevant, PBS listed treatments for CCA which require information on *IDH1* variant status.

For private health insurance purposes, item 73319 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 [Health Insurance \(Accredited Pathology Laboratories-Approval\) Principles 2017](#).

Why are the changes being made?

In November 2024, MSAC supported application 1750 for listing of a new MBS item for *IDH1* variant testing of tumour tissue, to determine patient eligibility for treatment with ivosidenib in patients with CCA. MSAC noted that in November 2024, the PBAC recommended that ivosidenib (Tibsovo®) be listed on the PBS for the treatment of adult patients with locally advanced or metastatic CCA who have previously progressed on chemotherapy and have a confirmed *IDH1* variant.

[\(MSAC 1750 public summary document\)](#)

What does this mean for requestors?

The new test will be for determining eligibility of CCA patients for ivosidenib and any future treatments listed on the PBS for this patient group, which require evidence of the presence of an *IDH1* variant. It is expected that the test will be requested by specialists and consultant physicians. The new item (73319) will also be pathologist-determinable, allowing pathologists to test for the *IDH1* variants following confirmation of CCA. Pathologist-determinable requests enable pathologists to claim for services without needing a request form. It was noted by MSAC that this approach will enable effective use of diagnostic tissue samples, allowing the laboratory to proceed directly from histological confirmation of CCA to molecular testing.

How will these changes affect patients?

CCA accounts for 3% of gastrointestinal cancers, which are broadly classified as intrahepatic (iCCA) or extrahepatic (eCCA) cancers. The prognosis for CCA is poor due to the aggressive nature of the disease (typically advanced at diagnosis) and lack of effective treatment options. From 1 July 2025, patients with CCA will be able to access a Medicare rebated test to detect *IDH1* variants in their tumour tissue to determine eligibility for treatment with ivosidenib and any future, relevant, PBS listed treatments for CCA which require information on *IDH1* variant status.

Who was consulted on the changes?

The following organisations were contacted as part of the MSAC targeted consultation process:

- Australasian Gastro-Intestinal Trials Group
- Australian Genomic Cancer Medicine Centre Limited (and affiliate Omico)
- Australian Pathology
- Cholangiocarcinoma Foundation Australia
- Clinical Oncological Society of Australia
- Gastroenterological Society of Australia
- GI Cancer Institute
- Medical Oncology Group of Australia (specialty society of RACP)
- Pancare Foundation
- Private Cancer Physicians of Australia
- Public Pathology Australia
- Rare Cancers Australia
- Royal College of Pathologists of Australasia

The parties that responded were supportive of the proposed new MBS item.

How will the changes be monitored and reviewed?

Providers must ensure that Medicare services requested or claimed using their provider number meet all legislative requirements. These services should also be considered acceptable by a general body of their profession. All Medicare claiming and requesting is subject to compliance checks. Providers or requesters may be required to submit evidence about the services they bill or request and should retain adequate and contemporaneous records. More information about the Department of Health, Disability and Ageing (the department) 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 July 2025)

Category 6 – Pathology Services

Group P7 - Genetics

73319

Detection in tumour tissue of isocitrate dehydrogenase 1 (*IDH1*) variant status, in a patient with histologically confirmed cholangiocarcinoma, to determine eligibility for a relevant treatment listed under the Pharmaceutical Benefits Scheme.

Applicable only once per lifetime

Fee: \$340.00 Benefit: 75% = \$255.00 85% = \$289.00

(See para PN.1.2 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.