

New MBS item for prognostic gene expression profile test to determine the risk of early and late metastasis in node negative and positive cancer under endocrine treatment

Last updated: 22 November 2023

- On 1 November 2023, a new pathology item was introduced on the Medicare Benefits Schedule (MBS) for a gene expression profiling test for patients who have certain types of early breast cancer
- This will result in improved prognosis for patients with certain types of breast cancer

What are the changes?

On 1 November 2023, a new MBS item commenced for a prognostic gene expression profile test to determine the risk of early and late metastasis in node negative and positive cancer under endocrine treatment. **Attachment A** to this factsheet lists the new item.

A gene expression profiling test called EndoPredict is a genetic test that looks at the expression levels of several genes that can be involved in breast cancer. It then combines their results with other clinical information to calculate a score. The score provides a patient's risk of getting breast cancer again, called recurrent breast cancer. Patients who have certain types of early breast cancer and are at intermediate risk of recurrence can use the score to estimate their likely future risk of cancer recurrence after surgery.

For private health insurance purposes, item 73306 has been listed under the following clinical category and procedure type:

- Private Health Insurance Classification:
- Clinical category: Support List (pathology)
- Procedure type: Type C

Why are the changes being made?

Knowing their prognosis is valuable for patients and their clinicians. The listing of this service was recommended by the Medical Services Advisory Committee (MSAC) in July 2022. Further details about MSAC applications can be found under <u>MSAC Applications</u> on the MSAC website (<u>Medical Services Advisory Committee</u>). The MSAC accepted that for patients who are at intermediate risk of recurrence, EndoPredict has some prognostic value

beyond the other information that clinicians and patients already use to estimate the risk of cancer recurrence.

What does this mean for requestors and providers?

Medical practitioners who have patients with certain types of early breast cancer and who are at intermediate risk of recurrence can use the score to estimate the likely future risk of their patient suffering cancer recurrence after surgery.

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?

Patients with certain types of early breast cancer can now access a test with improved prognostic value.

Who was consulted on the changes?

Consultation feedback was received from The Breast Cancer Network Australia.

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:

New item descriptor (commenced 1 November 2023)

Category 6 – Pathology Services

Group P7 – Genetics

73306

Gene expression profiling testing using EndoPredict, for the purpose of profiling gene expression in formalin-fixed, paraffin-embedded primary breast cancer tissue from core needle biopsy or surgical tumour sample to estimate the risk of distant recurrence of breast cancer within 10 years, if:

(a) the sample is from a new primary breast cancer, which is suitable for adjuvant chemotherapy; and

(b) the sample has been determined to be oestrogen receptor positive and HER2 negative by IHC and ISH respectively on surgically removed tumour; and

(c) the sample is axillary node negative or positive (up to 3 nodes) with a tumour size of at least 1 cm and no more than 5 cm determined by histopathology on surgically removed tumour; and

(d) the sample has no evidence of distal metastasis; and

(e) pre-testing of intermediate risk of distant metastases has shown that the tumour is defined by at least one of the following characteristics:

(i) histopathological grade 2 or 3;

(ii) one to 3 lymph nodes involved in metastatic disease (including micrometastases but not isolated tumour cells); and

(f) the service is not administered for the purpose of altering treatment decisions

Applicable once per new primary breast cancer diagnosis for any particular patient

MBS Fee: \$1,200

Benefit: 75% = \$900.00 85% =\$1,101.30 (Greatest Permissible Gap (GPG) will apply)

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.