# Amendment to MBS item 72814 for programmed death ligand 1 (PD-L1) immunohistochemistry (IHC) testing to include testing for advanced triple negative breast cancer (TNBC) patients

Last updated: 10 August 2023

- From 1 September 2023, the Medicare Benefits Schedule (MBS) item for PD-L1 IHC testing will be amended to include testing for patients with locally recurrent unresectable or metastatic TNBC (referred to in this paper as 'advanced TNBC').
- This change to MBS item 72814 will coincide with changes to the Pharmaceutical Benefits Scheme (PBS) to make pembrolizumab (Keytruda®) available to the same eligible patient population (commencing 1 September 2023).

### What are the changes?

Effective 1 September 2023, existing MBS item 72814 will be amended to expand access to PD-L1 IHC testing to patients with advanced TNBC. PD-L1 testing is a special test that measures how much of a protein called programmed death ligand 1 – or PD-L1 – is on the surface of cancer cells and the cells surrounding the cancer.

Patients with advanced TNBC whose tumours express a PD-L1 Combined Positive Score (CPS) ≥10 and who meet other criteria set out in the PBS, will be eligible for treatment with pembrolizumab (Keytruda®), which is due to be listed on the PBS from 1 September 2023 for this patient group.

For private health insurance purposes, item 72814 will continue to be listed under the following clinical category and procedure type:

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

# Why is this change being made?

The Pharmaceutical Benefits Advisory Committee (PBAC) recommended PBS listing of pembrolizumab (Keytruda®) for patients with advanced TNBC whose tumours express a PD-L1 of CPS ≥10 (commencing from 1 September 2023). Currently, MBS item 72814 allows for PD-L1 testing of tumour material from patients with non-small cell lung cancer or recurrent or

Medicare Benefits Schedule

Amendment to MBS item 72814 for programmed death ligand 1 (PDL1) immunohistochemistry (IHC) testing to include testing for advanced triple negative breast cancer (TNBC) patients 
Factsheet

Page 1 of 4

**MBS Online** 

metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx. This change will allow advanced TNBC patients to also access MBS funded PD-L1 testing to determine their eligibility for pembrolizumab (Keytruda®).

Inclusion of PD-L1 testing for advanced TNBC patients on the MBS was recommended by the Medical Services Advisory Committee (MSAC) in March 2023. Further details about MSAC applications can be found under <u>MSAC Applications</u> on the MSAC website (<u>Medical Services Advisory Committee</u>).

## What does this mean for requestors and providers?

Specialists who manage patients with diagnosed advanced TNBC can request MBS funded PD-L1 testing to determine if their patient is eligible for pembrolizumab (Keytruda®) through the PBS.

To be eligible for Medicare benefits, laboratories providing this service must be accredited according to the pathology accreditation standards specified in the *Health Insurance* (Accredited Pathology Laboratories-Approval) Principles 2017.

### How will these changes affect patients?

This MBS change will assist in providing greater access to testing and treatment for people with this type of cancer.

### Who was consulted on the changes?

Consultation was undertaken with key stakeholders, clinical experts and providers, and consumer health representatives as part of the MSAC and PBAC processes.

### 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 and information on other changes to the MBS can be found on the MBS Online website at <a href="www.mbsonline.gov.au">www.mbsonline.gov.au</a>. You can also subscribe to future MBS updates by visiting <a href="MBS Online">MBS Online</a> 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 <a href="mailto:askMBS@health.gov.au">askMBS@health.gov.au</a>.

Medicare Benefits Schedule

Amendment to MBS item 72814 for programmed death ligand 1 (PDL1) immunohistochemistry (IHC) testing to include testing for advanced triple negative breast cancer (TNBC) patients - Factsheet

Page 2 of 4

Private health insurance information on the product tier arrangements is available at <a href="https://www.privatehealth.gov.au">www.privatehealth.gov.au</a>. Detailed information on the MBS item listing within clinical categories is available on the <a href="https://pepartment's website">Department's website</a>. Private health insurance minimum accommodation benefits information, including MBS item accommodation classification, is available in the latest version of the <a href="https://private.nealth.gov.au">Private Health Insurance (Benefit Requirements) Rules 2011 found on the Federal Register of Legislation</a>. If you have a query in relation to private health insurance, you should email <a href="https://pepartments.gov.au">PHI@health.gov.au</a>.

Subscribe to 'News for Health Professionals' 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 Downloads page.

# Amended item descriptor (to take effect 1 September 2023)

#### Category 6 - Pathology Services

#### **Group P5 – Tissue Pathology**

#### 72814

Immunohistochemical examination by immunoperoxidase or other labelled antibody techniques using the programmed cell death ligand 1 (PD-L1) antibody of tumour material from a patient diagnosed with:

- (a) non-small cell lung cancer; or
- (b) recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx; or
- (c) locally recurrent unresectable or metastatic triple-negative breast cancer.

MBS fee: \$74.50

Benefit: 75% = \$55.90 85% = \$63.35

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.