

## New multi-indication PBS listing for two immunotherapy treatments from March 2026

(AUSTRALIA, Melbourne, SUNDAY 1 MARCH 2026) - Bristol Myers Squibb Australia (BMSA) confirms that OPDIVO® (nivolumab) and YERVOY® (ipilimumab) will be listed on the Pharmaceutical Benefits Scheme (PBS) for the treatment of immunotherapy sensitive advanced or metastatic cancer from March, 2026.<sup>1</sup>

Under this new listing, the Pharmaceutical Benefits Advisory Committee (PBAC) has recommended that clinicians use clinical judgement and discretion, guided by the best available clinical evidence, to determine if a person living with immunotherapy-sensitive advanced or metastatic cancer may benefit from nivolumab and/or ipilimumab.<sup>1,2</sup>

According to Medical Oncology Group of Australia Chair, A/Prof James Lynam, cancer specialists have gained clinical experience with these treatments since they were first registered with the Therapeutic Goods Administration (TGA) in 2011 (ipilimumab)<sup>3</sup> and 2016 (nivolumab).<sup>4</sup>

“The Medical Oncology Group of Australia welcomes the multi-indication listing of these two treatments on the Pharmaceutical Benefits Scheme. We know how important access to a broad range of appropriate therapeutic options is for people living with advanced cancers. As clinicians, we welcome the opportunity to provide those in our care with expanded treatment options. We will continue to individualise our patient’s care to ensure decisions are made thoughtfully, considering both potential benefits and risks.” said Prof Lynam.

Immunotherapy treatments, such as nivolumab and ipilimumab, support the body’s immune system to fight cancers.<sup>6,7</sup> Nivolumab can be used by itself or in combination with ipilimumab to target two distinct pathways, helping the immune system to recognise and attack cancer cells.<sup>3,4</sup> Between them, nivolumab and ipilimumab, have 26 TGA-registered indications and 17 PBS listings for both early-stage and advanced/metastatic cancers.<sup>3-5</sup> This PBS listing reflects the cumulative body of evidence for these medicines over time.<sup>1</sup>

Previously, PBS access to these immunotherapies has relied on assessment and reimbursement for individual cancer types one by one.<sup>1</sup> Today’s new listing changes this, marking a novel approach to PBS reimbursement by providing expanded access for people with immunotherapy sensitive advanced or metastatic cancers that may benefit from immunotherapy.<sup>1</sup>

After being diagnosed with Stage IV metastatic bowel cancer in 2019, at just 27 years old, Queensland woman Taylor Kirkwood knows too well the importance of access to a range of treatment options. When her cancer progressed following surgery and chemotherapy, Taylor was able to access an immunotherapy clinical trial recommended by her treating team.

“I was grateful I was able to take part in a clinical trial recommended by my doctor. It’s encouraging to see more treatment options become available to people like me.” Taylor said.

According to Bristol Myers Squibb General Manager, Australia and New Zealand, Owen Smith, the PBS listing is the culmination of years of advocacy and comes at a critical time

when debate around Australia's approach to Health Technology Assessments (HTA) has come into sharp focus.

“We have been working towards a multi-indication PBS listing for nivolumab and ipilimumab with the PBAC since 2017. We have maintained momentum throughout this period as we have always understood the importance and impact of expedited access for Australian patients.

Today we congratulate the PBAC and the Australian government for delivering this PBS listing which demonstrates how the system has evolved to reflect scientific and clinical advancements to ultimately meet the needs of patients.”

“We extend our deep thanks and appreciation to all those in the patient, advocacy, and clinical communities who have tirelessly championed the need for this expanded listing over many years. We also acknowledge the role of the Federal Minister for Health, the Hon Mark Butler MP, and The Department of Health, Disability and Ageing for ensuring today's listing became a reality.”

-ENDS-

#### **About IMMUNO-ONCOLOGY**

Immuno-oncology is based on the premise that the immune system is the body's most powerful and effective tool for recognising and fighting disease. Immunotherapy treatments are designed to engage the patient's own immune system to combat cancer by targeting the same immune pathways that tumour cells use to evade recognition and destruction.<sup>6,7</sup>

#### **About OPDIVO (nivolumab) and YERVOY (ipilimumab)**

Nivolumab and ipilimumab belong to a class of medicines known as checkpoint inhibitors, a type of immunotherapy.<sup>3,4</sup> Nivolumab is a programmed death-1 (PD-1) immune checkpoint inhibitor.<sup>3</sup> Ipilimumab is another immunotherapy from the class of checkpoint inhibitors which blocks the cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4).<sup>4</sup>

Both nivolumab and ipilimumab act on the immune system and, therefore, may cause inflammation.<sup>3,4</sup> Inflammation may cause serious damage to a patient's body, and some inflammatory conditions may be life-threatening.<sup>3,4</sup> Patients should be monitored continuously as an immune-related adverse reaction with nivolumab and ipilimumab may occur at any time during or after discontinuation of therapy.<sup>3,4</sup> Early identification of adverse reactions and appropriate intervention are an important part of using nivolumab and ipilimumab.<sup>3,4</sup>

The most common ( $\geq 10\%$ ) adverse events observed with nivolumab and ipilimumab as monotherapy or as a combination were rash, fatigue, diarrhoea, vomiting, nausea, abdominal pain, pruritus, hypothyroidism, hyperthyroidism, adrenal insufficiency, decreased appetite, headache, dizziness, dyspnoea, pyrexia, arthralgia and laboratory tests abnormalities.<sup>3,4</sup>

**For more information, please refer to the Consumer Medicine Information (CMI) for OPDIVO [[nivolumab](#)] and YERVOY [[ipilimumab](#)].**

#### **About advanced and metastatic cancer**

Advanced cancer is a term used to describe cancer that has spread, or returned (recurred) after treatment, and is unlikely to be cured.<sup>8</sup> It may refer to cancer that has spread to

nearby tissue (locally advanced cancer) or to distant parts of the body (metastatic cancer).<sup>8</sup>

**The new PBS listing applies to the following nivolumab and ipilimumab TGA registered indications:<sup>3,4</sup>**

- Nivolumab, as monotherapy, is indicated for the treatment of patients with unresectable or metastatic melanoma.
- Nivolumab, in combination with ipilimumab, is indicated for the treatment of patients with unresectable or metastatic melanoma. The approval of this indication is based on a pre-specified comparison to ipilimumab monotherapy. All analyses comparing nivolumab monotherapy with the nivolumab/ipilimumab combination are descriptive.
- Nivolumab, in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy, is indicated for the first-line treatment of patients with metastatic or recurrent non-small cell lung cancer (NSCLC) with no EGFR or ALK genomic tumour aberrations.
- Nivolumab, as monotherapy, is indicated for the treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) with progression on or after prior chemotherapy.
- Nivolumab, as monotherapy, is indicated for the treatment of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) with progression on or after prior chemotherapy. In patients with tumour EGFR or ALK genomic aberrations, OPDIVO should be used after progression on or after targeted therapy.
- Nivolumab, in combination with ipilimumab, is indicated for the first-line treatment of patients with unresectable malignant pleural mesothelioma.
- Nivolumab, in combination with ipilimumab, is indicated for the treatment of patients with intermediate/poor-risk, previously untreated advanced renal cell carcinoma.
- Nivolumab, in combination with cabozantinib, is indicated for the first-line treatment of patients with advanced renal cell carcinoma
- Nivolumab, as monotherapy, is indicated for the treatment of patients with advanced clear cell renal cell carcinoma after prior anti-angiogenic therapy.
- Nivolumab, as monotherapy, is indicated for the treatment of patients with relapsed or refractory classical Hodgkin lymphoma (cHL) after autologous stem cell transplant and treatment with brentuximab vedotin. The approval of this indication is based on objective response rate in a single arm study.
- Nivolumab, as monotherapy, is indicated for the treatment of recurrent or metastatic squamous cell cancer of the head and neck in patients progressing on or after platinum based therapy.
- Nivolumab, in combination with cisplatin and gemcitabine, is indicated for the first-line treatment of patients with unresectable or metastatic urothelial carcinoma.
- Nivolumab, as monotherapy, is indicated for the treatment of patients with locally advanced unresectable or metastatic urothelial carcinoma after prior platinum-containing therapy. The approval of this indication is based on objective response rate and duration of response in a single arm study.
- Nivolumab, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma.
- Nivolumab, as monotherapy, is indicated for the treatment of patients with hepatocellular carcinoma after prior sorafenib therapy. This indication is approved based on objective response rate and duration of response in a single arm study. An improvement in survival or disease-related symptoms has not been established.

- Nivolumab in combination with ipilimumab is indicated for the first-line treatment of patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression  $\geq 1\%$  as determined by a validated test.
- Nivolumab in combination with fluoropyrimidine- and platinum-based combination chemotherapy is indicated for the first-line treatment of patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression  $\geq 1\%$  as determined by a validated test.
- Nivolumab, as monotherapy, is indicated for the treatment of patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma after prior fluoropyrimidine and platinum based chemotherapy.
- Nivolumab, in combination with fluoropyrimidine- and platinum-based combination chemotherapy, is indicated for the first-line treatment of patients with HER2 negative advanced or metastatic gastric or gastro-oesophageal junction or oesophageal adenocarcinoma.
- Nivolumab in combination with ipilimumab is indicated for the treatment of adult patients with unresectable or metastatic colorectal cancer (CRC) that is MSI-H or dMMR as determined by a validated test.
- Ipilimumab, as monotherapy, is indicated for the treatment of patients with unresectable or metastatic melanoma.
- Ipilimumab, in combination with nivolumab, is indicated for the treatment of patients with unresectable or metastatic melanoma. The approval of this indication is based on a pre-specified comparison to ipilimumab monotherapy. All analyses comparing nivolumab monotherapy with the nivolumab/ipilimumab combination are descriptive.
- Ipilimumab, in combination with nivolumab, is indicated for the treatment of patients with intermediate/poor-risk, previously untreated advanced renal cell carcinoma.
- Ipilimumab, in combination with nivolumab and 2 cycles of platinum-doublet chemotherapy, is indicated for the first-line treatment of patients with metastatic or recurrent non-small cell lung cancer (NSCLC) with no EGFR or ALK genomic tumour aberrations.
- Ipilimumab, in combination with nivolumab, is indicated for the first-line treatment of patients with unresectable malignant pleural mesothelioma.
- Ipilimumab in combination with nivolumab is indicated for the first-line treatment of patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression  $\geq 1\%$  as determined by a validated test.
- Ipilimumab in combination with nivolumab is indicated for the treatment of adult patients with unresectable or metastatic colorectal cancer (CRC) that is MSI-H or dMMR as determined by a validated test.
- Ipilimumab, in combination with nivolumab, is indicated for the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma.

### Disclosure

Bristol Myers Squibb supports disclosure and transparency on interactions between the healthcare industry and healthcare professionals to ensure public trust and confidence. No expert spokespeople have been offered compensation for their involvement in this medical media campaign. All expert spokespeople have been briefed on the approved use of this product and their obligations with regard to promotion to the medical profession.

### About Bristol Myers Squibb™

Bristol Myers Squibb™ is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases.

For more information about Bristol Myers Squibb™, visit us at [BMS.com](https://www.bms.com) or follow us on [LinkedIn](#), [Twitter](#), [YouTube](#), [Facebook](#) and [Instagram](#).

### **Bristol Myers Squibb: Creating a Better Future for People with Cancer**

Bristol Myers Squibb is inspired by a single vision – transforming patients’ lives through science. The goal of the company’s cancer research is to deliver medicines that offer each patient a better, healthier life, and to make cure a possibility.

Building on a legacy across a broad range of cancers that have changed survival expectations for many, Bristol Myers Squibb researchers are exploring new frontiers in personalised medicine and, through innovative digital platforms, are turning data into insights that sharpen their focus. Deep understanding of causal human biology, cutting-edge capabilities, and differentiated research platforms uniquely position the company to approach cancer from every angle.

Cancer can have a relentless grasp on many parts of a patient’s life, and Bristol Myers Squibb is committed to taking actions to address all aspects of care, from diagnosis to survivorship. As a leader in cancer care, Bristol Myers Squibb is working to empower all people with cancer to have a better future.

Further information is available on request from Bristol Myers Squibb Australia Pty Ltd, ABN 33 004 333 322, Level 2, 4 Nexus Court, Mulgrave, VIC, 3170. ™ Trademark. Prepared: January 2024. 1425-AU-2400002.

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