KEYTRUDA® (pembrolizumab) INDICATIONS AND ACCESS FOR PATIENTS

KEYTRUDA may be accessed via the following:

PBS: Please refer to the PBS Schedule for full authority information at www.pbs.gov.au[1]

KEYTRUDA Co-Pay Program: Allows patients indicated for treatment with KEYTRUDA but not eligible for PBS reimbursement to access KEYTRUDA at a reduced cost. See information about the Co-Pay Program on page 5. For more information please email copay@msd.com or contact your Oncology Portfolio Manager.

Product Familiarisation Program (PFP): For information on current PFPs please contact mpt@msd.com or your Oncology Portfolio Manager.

INDICATION	ACCESS [RESTRICTIONS APPLY]		
	PBS[1]	CO-PAY PROGRAM**	PFP
MELANOMA			
As monotherapy for the treatment of unresectable or metastatic melanoma in adults.[2]	✓	✓	
As monotherapy for the adjuvant treatment of adult and adolescent (12 years and older) patients with Stage IIB, IIC, or III melanoma who have undergone complete resection.[2]	✓*	✓	✓^#
NON-SMALL CELL LUNG CANCER (NSCLC)			
In combination with pemetrexed and platinum chemotherapy, for the first-line treatment of patients with metastatic non-squamous NSCLC, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumour aberrations.[2]	✓	✓†	
In combination with carboplatin and either paclitaxel or nab-paclitaxel for the first-line treatment of patients with metastatic squamous NSCLC.[2]	✓	✓†	
As monotherapy for the first-line treatment of patients with NSCLC expressing programmed death receptor-ligand 1 (PD-L1) [tumour proportion score (TPS) ≥1%] as determined by a validated test, with no EGFR or ALK genomic tumour aberrations, and is • stage III where patients are not candidates for surgical resection or definitive chemoradiation, or • metastatic[2]	✓*	✓	
As monotherapy for the treatment of patients with advanced NSCLC whose tumours express PD-L1 with a ≥1% TPS as determined by a validated test and who have received platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumour aberrations should have received prior therapy for these aberrations prior to receiving KEYTRUDA.[2]		✓	
As monotherapy for the adjuvant treatment of patients with Stage IB (T2a ≥4 cm), II or IIIA NSCLC who have undergone complete resection and platinum-based chemotherapy.[2]		✓	

* Only a sub-population of this indication is PBS listed. Please review PBS Schedule for full authority information.[1]

** Eligibility criteria apply. For further information, about the KEYTRUDA Co-Pay Program, please contact copay@msd.com. Phone: 612 8988 8896 or 1800 093 766.

^ Eligibility criteria apply. For further information about PFPs, please contact mpt@msd.com. Phone: 1800 093 766.

Stage IIB & IIC. †KEYTRUDA only.

INDICATION	ACCESS [RESTRICTIONS APPLY]		
	PBS[1]	CO-PAY PROGRAM**	PFP
HEAD AND NECK SQUAMOUS CELL CANCER (HNSCC)			
As monotherapy or in combination with platinum and 5-fluorouracil (5-FU) chemotherapy for the first-line treatment of patients with metastatic or unresectable recurrent HNSCC, and whose tumours express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by a validated test.[2]	✓*	✓†	
As monotherapy for metastatic or unresectable recurrent HNSCC with disease progression on or after platinum-containing chemotherapy and whose tumours express PD-L1 [CPS ≥1] as determined by a validated test.[2]		✓	
CLASSICAL HODGKIN LYMPHOMA (cHL)			
As monotherapy for the treatment of adult and paediatric patients with relapsed or refractory cHL: 1. following autologous stem cell transplant (ASCT) or 2. following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option.[2] The approval of this indication in paediatric patients is on the basis of objective response rate from patients aged 11 years and older from single arm trial data and extrapolation from adult data.[2]	✓	✓	
PRIMARY MEDIASTINAL B-CELL LYMPHOMA (PMBCL)			
For the treatment of adult and paediatric patients with refractory PMBCL, or who have relapsed after 2 or more prior lines of therapy. The approval of this indication is on the basis of objective response rate and duration of response from non-randomised studies.[2]	✓	✓	
UROTHELIAL CARCINOMA (UC)			
As monotherapy for the treatment of patients with locally advanced or metastatic UC who are not eligible for any platinum-containing chemotherapy. This indication is approved based on overall response rate and duration of response in a single-arm study. Improvements in overall survival, progression-free survival, or health-related quality of life have not been established.[2]		✓	
As monotherapy for the treatment of patients with locally advanced or metastatic UC who have received platinum-containing chemotherapy.[2]	✓	✓	
For the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in-situ (CIS) with or without papillary tumours who are ineligible for or have elected not to undergo cystectomy. This indication was approved via the **provisional approval** pathway based on complete response rate and duration of response. Continued approval of this indication depends on verification and description of benefit in confirmatory trials.[2]		✓	

* Restrictions apply - review PBS schedule for full authority information.[1]

** Eligibility criteria apply. For further information, about the KEYTRUDA Co-Pay Program, please contact copay@msd.com. Phone: 612 8988 8896 or 1800 093 766.

† KEYTRUDA only.

INDICATION	ACCESS [RESTRICTIONS APPLY]		
	PBS[1]	CO-PAY PROGRAM**	PFP
MICROSATELLITE INSTABILITY-HIGH CANCER (MSI-H) OR MISMATCH REPAIR DEFICIENT (dMMR) CANCER			
Non-Colorectal For the treatment of adult and paediatric patients with unresectable or metastatic solid tumours that are MSI-H or dMMR, as determined by a validated test, that have progressed following prior treatment and when there are no satisfactory alternative treatment options.[2]		✓	
Colorectal For the treatment of patients with unresectable or metastatic colorectal cancer (CRC) that is MSI-H or dMMR as determined by a validated test.[2]	✓*	✓	
ENDOMETRIAL CARCINOMA			
In combination with lenvatinib for the treatment of patients with advanced endometrial carcinoma that is not MSI-H or dMMR, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.[2]	✓	✓†	
CERVICAL CANCER			
In combination with platinum chemotherapy and paclitaxel, with or without bevacizumab, for the treatment of patients with persistent, recurrent, or metastatic cervical cancer whose tumours express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by a validated test.[2]	✓	✓†	
RENAL CELL CARCINOMA (RCC)			
In combination with axitinib for the first-line treatment of patients with advanced RCC.[2]		✓†	
In combination with lenvatinib for the first-line treatment of adult patients with advanced RCC.[2]	✓	✓†	
As monotherapy for the adjuvant treatment of patients with RCC with a clear cell component who are at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.[2]		✓	
CUTANEOUS SQUAMOUS CELL CARCINOMA (cSCC)			
As monotherapy for the treatment of adult patients with recurrent or metastatic cSCC or locally advanced cSCC that is not curable by surgery or radiation. This indication was approved via the **provisional approval** pathway based on objective response rate and duration of response from a single-arm study. Improvements in overall survival, progression-free survival, or health-related quality of life have not been established. Full registration for this indication depends on submission of further clinical data to confirm the clinical benefit of the medicine.[2]		✓	
OESOPHAGEAL CANCER			
In combination with platinum and fluoropyrimidine based chemotherapy, for the first-line treatment of patients with locally advanced or metastatic carcinoma of the oesophagus or HER2 negative gastroesophageal junction adenocarcinoma (tumour centre 1 to 5 centimetres above the gastroesophageal junction) that is not amenable to surgical resection or definitive chemoradiation.[2]		✓†	

* Only PBS listed for unresectable or metastatic dMMR CRC. Please review PBS schedule for full authority information.[1]

† KEYTRUDA only.

** Eligibility criteria apply. For further information, about the KEYTRUDA Co-Pay Program, please contact copay@msd.com. Phone: 612 8988 8896 or 1800 093 766.

INDICATION	ACCESS [RESTRICTIONS APPLY]		
	PBS[1]	CO-PAY PROGRAM**	PFP
TUMOUR MUTATIONAL BURDEN-HIGH (TMB-H) CANCER			
For the treatment of adult and paediatric patients with unresectable or metastatic TMB-H [≥10 mutations/megabase (mut/Mb)] solid tumours, as determined by a validated test, that have progressed following prior treatment and who have no satisfactory alternative treatment options. This indication was approved via the **provisional approval** pathway, based on the pooling of data on objective response rate and response duration across multiple different tissue types in a single-arm trial. The assumption that TMB-H status is predictive of the treatment effect of KEYTRUDA for every tissue type has not been verified. Full registration for this indication depends on verification and description of clinical benefit in confirmatory trials.[2]		✓	
TRIPLE-NEGATIVE BREAST CANCER (TNBC)			
For the treatment of patients with high-risk early-stage TNBC in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery.[2]	✓	✓†	
In combination with chemotherapy, is indicated for the treatment of patients with locally recurrent unresectable or metastatic TNBC whose tumours express PD-L1 (CPS ≥10) as determined by a validated test and who have not received prior chemotherapy for metastatic disease.[2]	✓	✓†	

KEYTRUDA CO-PAY PROGRAM

INTRODUCTION

The KEYTRUDA Co-Pay program is available for eligible patients wishing to access KEYTRUDA for an ARTG-registered indication that is not reimbursed by the PBS.[1,2]

HOW MUCH WILL IT COST PATIENTS?

The KEYTRUDA Co-Pay program is divided into two phases. Patients are initiated in the Phase 1 program and continue in this program until a spend of $61,824 is reached. Once this occurs, the patient is eligible to be enrolled in the Phase 2 program.

Phase 1*: The total program cost of $61,824 is paid equally per cycle over 14 months.

Phase 2*: KEYTRUDA is supplied free of charge for up to an additional 10 months.

*For both phases, fees stated do not include compounding and dispensing fees.

HOW TO ENROL A PATIENT IN THE KEYTRUDA CO-PAY PROGRAM

1. Register and log into **www.MSDAccess.com**
2. Under “Search New Program” type in “AU KEYTRUDA”
3. AU KEYTRUDA (pembrolizumab) Co-Pay Program V2 (commenced 2023) will appear under the search bar
4. Next to the program name select “More”
5. Select “Enrol Patient” (top right)

Please see the full Terms and Conditions and Eligibility Criteria of the KEYTRUDA Co-Pay program on www.msdaccess.com for more information.
For further queries about the program, the MSD Medical Project team is available to support you: Email: mpt@msd.com. Phone: 1800 093 766 or 1800 066 426.

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† KEYTRUDA only.

SELECTED SAFETY INFORMATION

PRECAUTIONS: Immune-mediated adverse reactions (ImARs), incl. severe and fatal cases, have occurred in patients receiving KEYTRUDA. These have included, but not limited to: pneumonitis, colitis, hepatitis, hepatoxicity (in combination with axitinib), nephritis, endocrinopathies (adrenal insufficiency, hypophysitis, type 1 diabetes mellitus, hyperthyroidism, hypothyroidism, thyroiditis), severe skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis and bullous pemphigoid), uveitis, myositis, Guillain-Barre syndrome, pancreatitis, encephalitis, sarcoidosis, myasthenic syndrome/myasthenia gravis (incl. exacerbation), myelitis, vasculitis, hypoparathyroidism, gastritis, haemolytic anaemia, myocarditis, pericarditis and pericardial effusion, peripheral neuropathy, sclerosing cholangitis, exocrine pancreatic insufficiency, solid organ transplant rejection, severe infusion reactions (hypersensitivity, anaphylaxis) and complications of allogeneic HSCT.[2]

ImARs have occurred after discontinuation of treatment with KEYTRUDA. ImARs can affect more than one body system simultaneously.[2]

CONTRAINDICATIONS: None.[2]

ADVERSE EVENTS: In studies of unresectable or metastatic melanoma or mNSCLC (n=2799), the most common treatment-related serious adverse events were: pneumonitis, colitis, diarrhoea, and pyrexia. The most common treatment-related adverse reactions (reported in >10% of patients) were: fatigue, pruritus, rash, diarrhoea, and nausea. Refer to the Product Information for further safety information.[2]

PAEDIATRIC PATIENTS: There is limited experience with KEYTRUDA in paediatric patients. Efficacy for paediatric patients with melanoma, relapsed or refractory cHL, PMBCL, or MSI-H/dMMR cancers or TMB-H cancers, is extrapolated from the results in the respective adult populations. Efficacy has not been established in other paediatric malignancies.[2]

KEYTRUDA is not listed on the PBS for certain indications. PBS information can be viewed at www.pbs.gov.au

▼ This medicinal product is subject to additional monitoring in Australia due to provisional approval of an extension of indication. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.[2]

Please review full Production Information before prescribing available at www.msdinfo.com.au/keytrudapi or by scanning this QR code.

References: 1. Australian Government, Department of Health. The Pharmaceutical Benefits Scheme. Available at: www.pbs.gov.au. Accessed: May 2024.
2. KEYTRUDA Australian Approved Product Information www.msdinfo.com.au/keytrudapi.

Merck Sharp & Dohme (Australia) Pty Limited. Level 1 - Building A, 26 Talavera Rd, Macquarie Park, NSW 2113.
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