KEYTRUDA®
(pembrolizumab)

A Key To More Possibilities For Treating Your Patients*

*KEYTRUDA is available for multiple indications in Australia. See inside for full indications and dosing information.[1]

Contains **PBS codes** and **STREAMLINED authority codes** for relevant indications

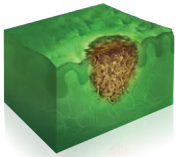
Updated September 2024

Menu

Solid tumours

Haematological tumours

Melanoma (metastatic)



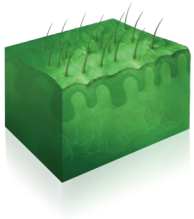
KEYTRUDA is indicated as monotherapy for the treatment of unresectable or metastatic melanoma in adults.[1]

PBS Information: Authority required (STREAMLINED).[2]
Further criteria apply, please see: www.pbs.gov.au

Treatment phase	Regimen	STREAMLINED code(s)	PBS code(s)	Max amount	No. of repeats
Initial treatment	200 mg Q3W	14818	Public: 10493G Private: 10475H	200 mg	5
Continuing treatment		10705	Public: 10436G Private: 10424P		7
Initial treatment	400 mg Q6W	14817	Public: 12128H Private: 12122B	400 mg	2
Continuing treatment		10701	Public: 12124D Private: 12123C		3

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.
Q3W: every 3 weeks. **Q6W:** every 6 weeks.

Melanoma (adjuvant treatment)



KEYTRUDA is indicated 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.[1]

†There is limited experience with KEYTRUDA in adolescent patients (12 years and older) with Stage IIB / IIC melanoma and no data for adolescent patients with Stage III melanoma.

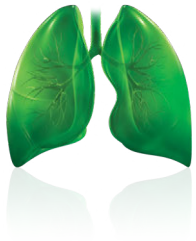
PBS Information: Authority required.[1,2]
Further criteria apply, please see: www.pbs.gov.au
Only adjuvant treatment with Stage IIIB / IIIC / IIID melanoma is PBS listed.

Treatment phase	Regimen	PBS code(s)	Max amount	No. of repeats
Initial treatment*	Adult: 200 mg Q3W Paediatric: 2 mg/kg‡ Q3W	Public: 12130K Private: 12120X	200 mg	7
Continuing treatment*				
Initial treatment*	Adult: 400 mg Q6W	Public: 12127G Private: 12125E	400 mg	3
Continuing treatment*				

*Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.
‡The recommended dose of KEYTRUDA in paediatric patients is 2 mg/kg (up to a maximum of 200 mg every 3 weeks).

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.
Q3W: every 3 weeks. **Q6W:** every 6 weeks.

Non-Small Cell Lung Carcinoma (NSCLC)



KEYTRUDA is indicated as monotherapy for the first-line treatment of patients with NSCLC expressing PD-L1 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.[1]

KEYTRUDA is indicated in combination with pemetrexed and platinum chemotherapy, for the first-line treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumour aberrations.[1]

KEYTRUDA is indicated in combination with carboplatin and either paclitaxel or nab-paclitaxel, for the first-line treatment of patients with metastatic squamous NSCLC.[1]

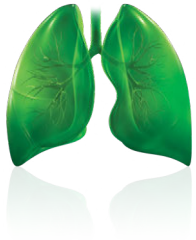
PBS Information: Authority required (STREAMLINED).[2]
Further criteria apply, please see: www.pbs.gov.au
Only Stage IV (metastatic) NSCLC is PBS listed.

Treatment phase	Regimen	STREAMLINED code(s)	PBS code(s)	Max amount	No. of repeats
Initial treatment*	200 mg Q3W	13431	Public: 11494Y Private: 11492W	200 mg	6
Continuing treatment*		13432			
Initial treatment‡	400 mg Q6W	13436	Public: 12119W Private: 12121Y	400 mg	3
Continuing treatment‡		13437			

*The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first.
‡The treatment must not exceed a total of 18 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.
Q3W: every 3 weeks. **Q6W:** every 6 weeks.

Non-Small Cell Lung Carcinoma (NSCLC)



KEYTRUDA is indicated 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 before receiving KEYTRUDA.[1]

KEYTRUDA is indicated 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.[1]

KEYTRUDA, in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment, is indicated for the treatment of patients with resectable Stage II, IIIA, or IIIB (T3-4N2) NSCLC.[1]

KEYTRUDA is not PBS listed for these indications.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.

Urothelial Carcinoma

KEYTRUDA is indicated as monotherapy for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have received platinum-containing chemotherapy.[1]

PBS Information: Authority required (STREAMLINED).[1,2]
Further criteria apply, please see: www.pbs.gov.au

Treatment phase	Regimen	STREAMLINED code(s)	PBS code(s)	Max amount	No. of repeats
Initial treatment	200 mg Q3W	13739	Public: 11646Y Private: 11632F	200 mg	6
Continuing treatment*		13736			
Initial treatment	400 mg Q6W	13739		400 mg	3
Continuing treatment*		13736			

*Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.
Q3W: every 3 weeks. **Q6W:** every 6 weeks.

Urothelial Carcinoma

KEYTRUDA is indicated as monotherapy for the treatment of patients with locally advanced or metastatic urothelial carcinoma 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.[1]

KEYTRUDA is indicated for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in-situ 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.[1]

KEYTRUDA is not PBS listed for these indications.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.

Endometrial Carcinoma

KEYTRUDA, in combination with lenvatinib, is indicated 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.[1]

KEYTRUDA PBS Information: Authority required (STREAMLINED).[2]
Further criteria apply, please see: www.pbs.gov.au

Treatment phase	Regimen	STREAMLINED code(s)	PBS code(s)	Max amount	No. of repeats
Initial treatment	200 mg Q3W	14027	Public: 13286G Private: 13287H	200 mg	6
Continuing treatment*		14044			
Initial treatment	400 mg Q6W	14027		400 mg	3
Continuing treatment*		14044			

*Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.

For information related to the lenvatinib streamlined authority, please refer to the PBS schedule at www.pbs.gov.au

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.
Q3W: every 3 weeks. **Q6W:** every 6 weeks.

Head and Neck Squamous Cell Carcinoma (HNSCC)

KEYTRUDA as monotherapy or in combination with platinum and 5-fluorouracil (5-FU) chemotherapy, is indicated 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.[1]

PBS Information: Authority required (STREAMLINED).[1,2]
Further criteria apply, please see: www.pbs.gov.au

Treatment phase	Regimen	STREAMLINED code(s)	PBS code(s)	Max amount	No. of repeats
Initial treatment	200 mg Q3W	13735	Public: 13131D Private: 13114F	200 mg	6
Continuing treatment*		13731			
Initial treatment	400 mg Q6W	13735		400 mg	3
Continuing treatment*		13731			

*Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.
Q3W: every 3 weeks. **Q6W:** every 6 weeks.

Head and Neck Squamous Cell Carcinoma (HNSCC)

KEYTRUDA is indicated as monotherapy for the treatment of patients with metastatic or unresectable recurrent HNSCC with disease progression on or after platinum-containing chemotherapy and whose tumours express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by a validated test.[1]

KEYTRUDA is not PBS listed for this indication.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.
Q3W: every 3 weeks. **Q6W:** every 6 weeks.

Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Colorectal Cancer

KEYTRUDA is indicated for the treatment of patients with unresectable or metastatic colorectal cancer (CRC) that is MSI-H or dMMR as determined by a validated test.[1]

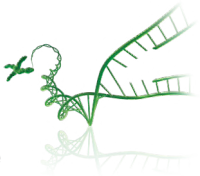
PBS Information: Authority required.[2]
Further criteria apply, please see: www.pbs.gov.au
PBS listed for patients untreated for this indication with dMMR CRC as determined by a immunohistochemistry test.

Treatment phase	Regimen	PBS code(s)	Max amount	No. of repeats
Initial treatment	200 mg Q3W	Public: 12615Y Private: 12605K	200 mg	6
Continuing treatment*				
Initial treatment	400 mg Q6W		400 mg	3
Continuing treatment*				

*Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.
Q3W: every 3 weeks. **Q6W:** every 6 weeks.

Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Cancer



KEYTRUDA is indicated 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.[1]

KEYTRUDA is not PBS listed for this indication.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.

Renal Cell Carcinoma (RCC)

KEYTRUDA, in combination with lenvatinib, is indicated for the first-line treatment of adult patients with advanced RCC.[1]

KEYTRUDA PBS Information: Authority required (STREAMLINED).[2]
Further criteria apply, please see: www.pbs.gov.au

Treatment phase	Regimen	STREAMLINED code(s)	PBS code(s)	Max amount	No. of repeats
Initial treatment	200 mg Q3W	13948	Public: 13254N Private: 13267G	200 mg	6
Continuing treatment*		13949			
Initial treatment	400 mg Q6W	13948		400 mg	3
Continuing treatment*		13949			

*Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.

For information related on the lenvatinib streamlined authority, please refer to the PBS schedule at www.pbs.gov.au

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.
Q3W: every 3 weeks. **Q6W:** every 6 weeks.

Renal Cell Carcinoma (RCC)

KEYTRUDA is indicated in combination with axitinib, for the first-line treatment of patients with advanced RCC.[1]

KEYTRUDA, as monotherapy, is indicated 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 (refer to the clinical trials section of the Product Information).[1]

KEYTRUDA is not PBS listed for these indications.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.

Cutaneous Squamous Cell Carcinoma (cSCC)

KEYTRUDA is indicated 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, and 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.[1]

KEYTRUDA is not PBS listed for this indication.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.

Gastric Cancer

KEYTRUDA, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction (GOJ) adenocarcinoma that is not HER2-positive.[1]

KEYTRUDA, in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or GOJ adenocarcinoma, whose tumours express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by a validated test.[1]

KEYTRUDA is not PBS listed for these indications.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.

Oesophageal Cancer

KEYTRUDA is indicated 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 1–5 cm above the gastroesophageal junction) that is not amenable to surgical resection or definitive chemoradiation.[1]

KEYTRUDA is not PBS listed for this indication.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.

Triple-Negative Breast Cancer (TNBC)

KEYTRUDA, 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.[1]

PBS Information: Authority required (STREAMLINED).[2]
Further criteria apply, please see: www.pbs.gov.au

Treatment phase	Regimen	STREAMLINED code	PBS code(s)	Max amount	No. of repeats
Initial treatment	200 mg Q3W	14324	Public: 13608F Private: 13626E	200 mg	6
Continuing treatment*					
Initial treatment	400 mg Q6W			400 mg	3
Continuing treatment*					

*Prescription must not extend PBS subsidy beyond 24 cumulative months from the first administered dose.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.
Q3W: every 3 weeks. **Q6W:** every 6 weeks.

Triple-Negative Breast Cancer (TNBC)

KEYTRUDA is indicated 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.[1]

PBS Information: Authority required (STREAMLINED).[2]
Further criteria apply, please see: www.pbs.gov.au

Treatment phase	Regimen	STREAMLINED code	PBS code(s)	Max amount	No. of repeats
Initial treatment	200 mg Q3W	14727	Public: 13752T Private: 13739D	200 mg	7
Continuing treatment*					
Initial treatment	400 mg Q6W			400 mg	4
Continuing treatment*					

*Patient must not be undergoing treatment with this drug beyond 52 cumulative weeks under this restriction.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.
Q3W: every 3 weeks. **Q6W:** every 6 weeks.

Cervical Cancer

KEYTRUDA, in combination with platinum chemotherapy and paclitaxel, with or without bevacizumab, is indicated 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.[1]

KEYTRUDA PBS Information: Authority required (STREAMLINED).[2]
Further criteria apply, please see: www.pbs.gov.au

Treatment phase	Regimen	STREAMLINED code(s)	PBS code(s)	Max amount	No. of repeats
Initial treatment	200 mg Q3W	14403	Public: 13635P Private: 13645E	200 mg	6
Continuing treatment*		14404			
Grandfather arrangements		14405			
Initial treatment	400 mg Q6W	14403		400 mg	3
Continuing treatment*		14404			
Grandfather arrangements		14405			

*Treatment must not exceed a total of (i) 24 months, (ii) 35 doses (based on a 3-weekly dose regimen), (iii) 17 doses (based on a 6-weekly dose regimen) whichever comes first from the first dose of this drug regardless if it was PBS/non-PBS subsidised.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.
Q3W: every 3 weeks. **Q6W:** every 6 weeks.

Tumour Mutational Burden-High Cancer (TMB-H)

KEYTRUDA is indicated for the treatment of adult and paediatric patients with unresectable or metastatic TMB-H (≥10 mutations/megabase) solid tumours, as determined by a validated test, that have progressed following prior treatment and when no satisfactory alternative treatment options are available.

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.[1]

KEYTRUDA is not PBS listed for this indication.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.

Biliary Tract Carcinoma (BTC)

KEYTRUDA, in combination with gemcitabine and cisplatin, is indicated for the treatment of patients with locally advanced unresectable or metastatic BTC.[1]

KEYTRUDA is not PBS listed for this indication.

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.

Classical Hodgkin Lymphoma

KEYTRUDA is indicated as monotherapy for the treatment of adult and paediatric patients with relapsed or refractory classical Hodgkin Lymphoma:

- following autologous stem cell transplant (ASCT) or
- following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option.

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.[1]

PBS Information: Authority required (STREAMLINED).[1,2]
Further criteria apply, please see: www.pbs.gov.au

Treatment phase	Regimen	STREAMLINED code(s)	PBS code(s)	Max amount	No. of repeats
Initial treatment	Adult: 200 mg Q3W Paediatric: 2 mg/kg† Q3W	13726	Public: 11330H Private: 11352L	200 mg	6
Continuing treatment*		13741			
Initial treatment	Adult: 400 mg Q6W	13726		400 mg	3
Continuing treatment*		13741			

*Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.
†The recommended dose of KEYTRUDA in paediatric patients is 2 mg/kg (up to a maximum of 200 mg every 3 weeks).

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.
Q3W: every 3 weeks. **Q6W:** every 6 weeks.

Primary Mediastinal B-Cell Lymphoma

KEYTRUDA is indicated for the treatment of adult and paediatric patients with refractory primary mediastinal B-cell lymphoma, or who have relapsed after two 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.[1]

PBS Information: Authority required (STREAMLINED).[1,2]
Further criteria apply, please see: www.pbs.gov.au

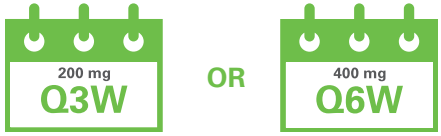
Treatment phase	Regimen	STREAMLINED code(s)	PBS code(s)	Max amount	No. of repeats
Initial treatment	Adult: 200 mg Q3W Paediatric: 2 mg/kg† Q3W	13727	Public: 12129J Private: 12126F	200 mg	6
Continuing treatment*		13732			
Initial treatment	Adult: 400 mg Q6W	13727		400 mg	3
Continuing treatment*		13732			

*Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.

†The recommended dose of KEYTRUDA in paediatric patients is 2 mg/kg (up to a maximum of 200 mg every 3 weeks).

Patients should be treated with the dosage of KEYTRUDA listed in the Product Information.
Q3W: every 3 weeks. **Q6W:** every 6 weeks.

Dosing information[1]



KEYTRUDA is administered as an intravenous infusion over 30 minutes. The recommended dose of KEYTRUDA in adults is either 200 mg Q3W or 400 mg Q6W.

KEYTRUDA was originally developed using 200 mg Q3W monotherapy dosing. The 400 mg Q6W dosing regimen has been approved based on pharmacokinetic and exposure-response modelling and simulations. Clinical endpoints data is not available. Refer to the Product Information (PI) for further information.

Treat with KEYTRUDA until disease progression or unacceptable toxicity, or up to 24 months in patients without disease progression or the equivalent number of treatment cycles for urothelial cancer (locally advanced or metastatic), NSCLC, HNSCC, PMBCL, MSI-H/dMMR cancers, BTC, cervical cancer, gastric or GOJ adenocarcinoma, cSCC or TMB-H cancers.

For use in combination, see the PI for the concomitant therapies. When administering KEYTRUDA as part of a combination with intravenous chemotherapy, KEYTRUDA should be administered first.

For the adjuvant treatment of melanoma, NSCLC, or RCC, KEYTRUDA should be administered for up to one year or until disease recurrence or unacceptable toxicity.

Q3W: every 3 weeks. **Q6W:** every 6 weeks.

For the treatment of high-risk BCG-unresponsive NMIBC, KEYTRUDA should be administered until persistent or recurrent high-risk NMIBC, disease progression, unacceptable toxicity or up to 24 months.

For the treatment of endometrial carcinoma that is not MSI-H or dMMR and RCC, KEYTRUDA should be administered as above in combination with lenvatinib 20 mg orally once daily until disease progression, unacceptable toxicity, or for KEYTRUDA, up to 24 months in patients without disease progression. Refer to the lenvatinib Product Information for recommended dosing information.

For the neoadjuvant and adjuvant treatment of high-risk early-stage TNBC, patients should be treated with neoadjuvant KEYTRUDA in combination with chemotherapy for 8 doses of 200 mg Q3W or 4 doses of 400 mg Q6W or until disease progression that precludes definitive surgery or unacceptable toxicity, followed by adjuvant treatment with KEYTRUDA as monotherapy for 9 doses of 200 mg Q3W or 5 doses of 400 mg Q6W or until disease recurrence or unacceptable toxicity. Patients who experience disease progression that precludes definitive surgery or unacceptable toxicity related to KEYTRUDA as neoadjuvant treatment in combination with chemotherapy should not receive KEYTRUDA monotherapy as adjuvant treatment.

For the neoadjuvant and adjuvant treatment of resectable NSCLC, patients should be treated with neoadjuvant KEYTRUDA in combination with chemotherapy for 12 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity, followed by adjuvant treatment with KEYTRUDA as monotherapy for 39 weeks or until disease recurrence or unacceptable toxicity.

Paediatric recommended dose 2 mg/kg (up to a maximum of 200 mg).

Selected safety information[1]

Precautions:
Immune-mediated adverse reactions (IMARs), including severe and fatal cases, have occurred in patients receiving KEYTRUDA. These have included, but not limited to: pneumonitis, colitis (incl. gastrointestinal perforation), 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 epidemal necrolysis and bullous pemphigoid), uveitis, myositis/polymyositis, 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, arthritis, solid organ transplant rejection, severe infusion reactions (hypersensitivity, anaphylaxis) and complications of allogeneic HSCT.

IMARs have occurred after discontinuation of treatment with KEYTRUDA. IMARs can affect more than one body system simultaneously.

Thyroid and liver function tests should be performed at baseline, periodically during treatment and as indicated based on clinical evaluation.

Withhold or discontinue KEYTRUDA to manage adverse reactions as described in the PI.

SAE: serious adverse event.

Contraindications: None.

Adverse events:
The safety of KEYTRUDA was evaluated in 2799 patients with unresectable or metastatic melanoma or metastatic NSCLC in controlled and uncontrolled studies. The most common treatment-related SAEs were: pneumonitis, colitis (including gastrointestinal perforation), 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 PI for further safety information.

Interactions:
None expected. Avoid systemic corticosteroids or immunosuppressants prior to treatment (except as premedication in combination with chemotherapy).

Selected safety information continued[1]

Special populations:
Paediatric patients: Efficacy for paediatric patients with melanoma, relapsed or refractory cHL, PMBCL, MSI-H/dMMR cancers, or TMB-H cancers, is extrapolated from the results in the respective adult populations and supported by data from KEYNOTE-051. Efficacy has not been established in other paediatric malignancies.

Pregnancy/lactation: Pregnancy Category D. Patients who could become pregnant should use effective contraception during treatment with KEYTRUDA and for at least 4 months following the last dose of KEYTRUDA. There is no information regarding the presence of KEYTRUDA in human milk, the absorption and effects on the breast-fed infant, or the effects on milk production. Patients should be advised not to breast-feed during treatment and for at least 4 months after the last dose.

Use in the elderly: No overall differences in safety or efficacy were reported between elderly patients (65+) and younger patients (<65). No dosage adjustment required.

Dosing in renal/hepatic impairment: No dose adjustment required for mild/moderate renal and mild hepatic impairment. KEYTRUDA has not been studied in severe renal or moderate/severe hepatic impairment.

Machinery operation: Fatigue has been reported with KEYTRUDA treatment so may influence ability to operate machinery/drive.

▼ 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.

KEYTRUDA is not listed on the PBS for certain indications.
PBS information can be viewed at www.pbs.gov.au
KEYTRUDA Product Information can be viewed at www.msdinfo.com.au/keytrudapi

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

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