Pr KEYTRUDA®
(pembrolizumab)

DETERMINING PD-L1 STATUS IN PATIENTS FOR SPECIFIC TUMOR TYPES.

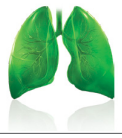
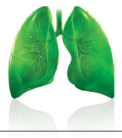
Programmed death-ligand 1 (PD-L1) expression

PD-L1 (Programmed Cell Death Ligand 1) modulates the activity of the immune system by exerting dual ligand blockade of the PD-1 pathway. It can also be found on tumor cells.[1]

PD-1 (Programmed Cell Death Protein 1) is an immune-checkpoint receptor that limits the activity of T lymphocytes in peripheral tissues by binding to PD-L1. There are cancer immunotherapies that target this pathway, but biomarker testing may be required to determine if a patient is eligible for those treatments.[2]

For specific indications, assessing PD-L1 expression at specific minimum thresholds are required to use KEYTRUDA®.[3]

PD-L1 testing is required for the following indications:[2]

	**1st line treatment, as monotherapy, for of adults patients with metastatic non-small cell lung carcinoma (NSCLC) or stage III disease where patients are not candidates for surgical resection or definitive chemoradiation expressing PD-L1 TPS≥ 1% as determined by a validated test, with no EGFR or ALK genomic tumor aberrations.**	Cut-off Point **TPS≥1%**
	**Treatment of adult patients with metastatic NSCLC as monotherapy, whose tumors express PD-L1 TPS≥ 1% as determined by a validated test, and who have disease progression on or after platinum-containing chemotherapy.**	Cut-off Point **TPS≥1%**
	**Treatment of adults patients with persistent, recurrent, or metastatic cervical cancer, whose tumors express PD-L1 CPS≥ 1, as determined by a validated test, in combination with chemotherapy with or without bevacizumab.**	Cut-off Point **CPS≥1**
	**1st line treatment of metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC) as monotherapy, in adult patients whose tumors have PD-L1 CPS≥ 1 as determined by a validated test.**	Cut-off Point **CPS≥1**
	**Treatment in combination with chemotherapy for adult with locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC), who have not received prior chemotherapy for metastatic disease and whose tumors express with PD-L1 CPS≥ 10, as determined by a validated test.**	Cut-off Point **CPS≥10**

CONSIDER BIOMARKER TESTING

Visit biomarkertesting.ca for more information.

Please consult the Product Monograph for important information about:

- Contraindications in people who have experienced a severe hypersensitivity reactions to this drug or to any ingredient in the formulation or component to the container closure system;
- Relevant warnings and precautions regarding immune-mediated adverse reactions, solid organ transplant rejection, allogeneic stem cell transplant after and before treatment, severe infusion-related reactions, teratogenic risk, patients with hepatic or renal impairment, pregnant women and women breastfeeding during treatment and for at least 4 months after it, driving and operating machinery, monitoring requirements, pediatrics, and geriatrics;
- Conditions of clinical use, adverse reactions, drug interactions and dosing instructions.

The Product Monograph is also available by calling us at 1-800-567-2594 or by email at medinfocanada@merck.com

ALK=Anaplastic Lymphoma Kinase; CPS=combined positive score; EGFR=Epidermal growth factor receptor; HNSCC=head and neck squamous cell carcinoma; NSCLC=non–small cell lung carcinoma; PD-L1=programmed death ligand 1; TNBC=triple–negative breast cancer; TPS=tumor proportion score.

References: 1. Chen DS *et al. Clin Cancer Res.* 2012;18(24):6580–6587. **2.** KEYTRUDA® Product Monograph. Merck Canada Inc., January 25, 2023. **3.** Incorvaia L, Fanale D, Badalamenti G, *et al.* Programmed Death Ligand 1 (PD-L1) as a Predictive Biomarker for Pembrolizumab Therapy in Patients with Advanced Non-Small-Cell Lung Cancer (NSCLC). *Adv Ther.* 2019;2600-2617. **4.** Herbst R, Garon E, *et al.* Five-Year Survival Update From KEYNOTE-010: Pembrolizumab Versus Docetaxel for Previously Treated, Programmed Death-Ligand 1–Positive Advanced NSCLC. *J Thorac Oncol.* 2021;P1718-1732.

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