PD-L1 Testing – Reimbursed indications[1] (latest revision 12/2025)

INDICATION	DISEASE STAGE	TREATMENT	ALGORITHM[2]	CUT-OFF	CLONES[3] used in registrational trial
Non-small cell lung cancer					
neo-adjuvant	Resectable, at high risk of recurrence	Nivolumab + platinum	TPS	≥ 1%	28-8 PharmDx assay
adjuvant	At high risk of recurrence after complete resection and adjuvant platinum-based chemotherapy	Atezolizumab	TC	≥ 50%	SP263 Ventana assay
1L	Metastatic, *with no EGFR or ALK positive tumor mutations*	Pembrolizumab	TPS	≥ 50%	- 22C3 PharmDx assay - 22C3 LDT - SP263 Ventana assay
	Locally advanced (chemoradiation-ineligible), or metastatic	Cemiplimab	TPS	≥ 50%	
	Locally advanced, unresectable, *with no EGFR, ALK or ROS1 gene alterations*	Cemiplimab + platinum	TPS	≥ 1%	
	Locally advanced, unresectable, *if no progression after platinum-based chemoradiotherapy*	Durvalumab	TPS	≥ 1%	
	Metastatic	Atezolizumab	TC	≥ 50%	SP142 Ventana assay
			IC	≥ 10%	
2L	Locally advanced or metastatic	Pembrolizumab	TPS	≥ 1%	- 22C3 PharmDx assay - 22C3 LDT - SP263 Ventana assay
Urothelial carcinoma					
adjuvant	Muscle invasive urothelial carcinoma (MIUC) at high risk of recurrence after radical resection	Nivolumab	TC	≥ 1%	28-8 PharmDx assay
1L	Locally advanced or metastatic, platinum-ineligible	Pembrolizumab	CPS	≥ 10	- 22C3 PharmDx assay - 22C3 LDT
	Locally advanced or metastatic, platinum-ineligible	Atezolizumab	IC	≥ 5%	SP142 Ventana assay
Head and Neck squamous cell carcinoma					
Perioperative	Resectable locally advanced	Pembrolizumab neoadjuvant followed by pembrolizumab adjuvant in combo with Radiotherapy ± cisplatin	CPS	≥ 1	- 22C3 PharmDx assay - 22C3 LDT
1L	Metastatic or unresectable recurrent	Pembrolizumab with or without platinum+5-FU	CPS	≥ 1 To be reported as CPS<1, CPS≥1 or CPS≥20	- 22C3 PharmDx assay - 22C3 LDT
Triple-negative Breast cancer					
1L	Unresectable locally advanced or metastatic	Pembrolizumab + chemotherapy	CPS	≥ 10	- 22C3 PharmDx assay - 22C3 LDT
HER2+ Gastric / GEJ cancer					
1L	Metastatic	Pembrolizumab + trastuzumab + platinum + flouropyrimidine	CPS	≥ 1	- 22C3 PharmDx assay - 22C3 LDT
HER2- Gastric / GEJ cancer					
1L	Advanced or metastatic	Nivolumab + platinum + fluoropyrimidine	CPS	≥ 5	28-8 PharmDx assay
	Locally advanced unresectable or metastatic	Pembrolizumab + platinum + fluoropyrimidine	CPS	≥ 1	- 22C3 PharmDx assay - 22C3 LDT
	Locally advanced unresectable or metastatic	Tislelizumab + platinum + fluoropyrimidine	TAP	≥ 5%	SP263 Ventana assay
Oesophageal squamous cell carcinoma					
1L	Locally advanced unresectable or metastatic	Pembrolizumab + platinum + fluoropyrimidine	CPS	≥ 10	- 22C3 PharmDx assay - 22C3 LDT
	Unresectable advanced, recurrent or metastatic	Nivolumab + platinum + fluoropyrimidine	TPS	≥ 1%	28-8 PharmDx assay
	Locally advanced unresectable or metastatic	Tislelizumab + platinum	TAP	≥ 5%	SP263 Ventana assay
Oesophageal adenocarcinoma					
1L	Locally advanced unresectable or metastatic	Pembrolizumab + platinum + fluoropyrimidine	CPS	≥ 10	- 22C3 PharmDx assay - 22C3 LDT
	Advanced or metastatic	Nivolumab + platinum + fluoropyrimidine	CPS	≥ 5	28-8 PharmDx assay
Cervical cancer					
1L	Persistent, recurrent, or metastatic	Pembrolizumab + chemotherapy + bevacizumab	CPS	≥ 1	- 22C3 PharmDx assay - 22C3 LDT
Melanoma					
1L	Advanced (unresectable or metastatic)	Nivolumab + relatlimab	TPS	< 1%	28-8 PharmDx assay

[1] Only drugs that are officially reimbursed in Belgium for the specific tumor indications are displayed on the poster. Website RIZIV / INAMI: pembrolizumab, durvalumab, atezolizumab, nivolumab, cemiplimab, tislelizumab (https://ondpanon.riziv.fgov.be/SSPWebApplicationPublic/fr/Public/ProductSearch or https://ondpanon.riziv.fgov.be/SSPWebApplicationPublic/nl/Public/ProductSearch)

[2] See website of the International Immuno-Oncology Working Group, https://pdl1.azurewebsites.net/ --- TPS = Tumor Proportion Score, TC = Tumor cell; IC = Immune Cell; CPS = Combined Positivity Score; TAP = Tumor Area Positivity

[3] Assays with 22C3, SP263 and 28-8 are interchangeable for most indications.

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New indications can be submitted via info@belgian-society-pathology.eu