

PD-L1 Testing – Reimbursed indications¹

(latest revision 06/2024)

INDICATION	DISEASE STAGE	TREATMENT	ALGORITHM ²	CUT-OFF	CLONES ³ used in registrational trial
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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 IC	≥ 50% ≥ 10%	SP142 Ventana assay
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

1L	Metastatic or unresectable recurrent	Pembrolizumab with or without platinum+5-FU	CPS	≥ 1 <small>To be reported as CPS<1, CPS≥1 or CPS≥20</small>	- 22C3 PharmDx assay - 22C3 LDT
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Triple-negative Breast cancer

1L	Unresectable locally advanced or metastatic	Pembrolizumab + chemotherapy	CPS	≥ 10	- 22C3 PharmDx assay - 22C3 LDT
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HER2+ Gastric / GEJ cancer

1L	Metastatic	Pembrolizumab + trastuzumab + platinum + fluoropyrimidine	CPS	≥ 1	- 22C3 PharmDx assay - 22C3 LDT
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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

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

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
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Melanoma

1L	Advanced (unresectable or metastatic)	Nivolumab + relatlimab	TPS	< 1%	28-8 PharmDx assay
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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 (<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://pd1.azurewebsites.net/> --- TPS = Tumor Proportion Score, TC = Tumor cell; IC = Immune Cell; CPS = Combined Positivity Score

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