Pembrolizumab

Essential medicine status ✓

Section: 8. Immunomodulators and antineoplastics > 8.2. Antineoplastics and supportive medicines > 8.2.3. Immunomodulators

ATC codes: L01FF02

Indication	Melanoma of skin ICD11 code: 2C30
INN	Pembrolizumab
Medicine type	Biological agent
List type	Core
Additional notes	*including quality-assured biosimilars
Formulations	Parenteral > General injections > IV: 25 mg per mL in 4 mL vial
EML status history	First added in 2025 (TRS 1064)
Sex	All
Age	Adolescents and adults
Therapeutic alternatives	nivolumab (ATC codes: L01FF01) Parenteral > General injections > IV: 10 mg per mL concentrate solution for infusion
Patent information	Main patent is active in several jurisdictions. For more information on specific patents and license status for developing countries visit www.MedsPal.org Read more about patents.
Tags	Cancer
Wikipedia	Pembrolizumab
DrugBank	Pembrolizumab

Summary of evidence and Expert Committee recommendations

With the 2025 recommendation to list pembrolizumab for first-line monotherapy of metastatic non-small cell lung cancer with high PD-L1 expression (≥ 50%), first-line monotherapy for deficient mismatch repair/microsatellite instability-high metastatic colorectal cancer, and in combination with platinum-based chemotherapy, as first-line treatment of metastatic cervical cancer with PD-L1 expression ≥ 1%, the Expert Committee recommended changing the current square box listing of nivolumab as the class representative and pembrolizumab as the specified therapeutic alternative for metastatic melanoma, to make pembrolizumab the class representative with nivolumab as the specified therapeutic alternative. This is intended to signal to countries the possibility of aggregating procurement of a single molecule, pembrolizumab, for multiple cancer indications, which can influence price negotiations with manufacturers. Limiting procurement fragmentation by focusing on a select few immune checkpoint inhibitors is likely to facilitate central purchasing through competitive tendering and better competition from pembrolizumab biosimilars, thereby increasing access.