Active substances set

Search phrase: Tracheal, bronchus, and lung cancer

Below you will find a list of active substances registered by the European Medical Agency (EMA) in the last 15 years, recommended by the European Society of Clinical Oncology (ESMO) and their reimbursement status in the country.

Tracheal, bronchus, and lung cancer

Ceritinib	Ceritinib as monotherapy is indicated for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC). Ceritinib as monotherapy is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib.	NO REIMBURSEMENT ESMO
Ramucirumab	Ramucirumab in combination with erlotinib is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer with activating epidermal growth factor receptor (EGFR) mutations. Ramucirumab in combination with docetaxel is indicated for the treatment of adult patients with locallyadvanced or metastatic non-small cell lung cancer with disease progression after platinum-based chemotherapy.	NO REIMBURSEMENT ESMO
Trametinib	Trametinib in combination with dabrafenib is indicated for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600 mutation.	NO REIMBURSEMENT ESMO
Dabrafenib	Dabrafenib in combination with trametinib is indicated for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600 mutation.	NO REIMBURSEMENT ESMO

Dacomitinib	Dacomitinib, as monotherapy, is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR)-activating mutations.	NO REIMBURSEMENT ESMO
Selpercatinib	Selpercatinib as monotherapy is indicated for the treatment of adults with: - advanced RET fusion-positive non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor; - advanced RET fusion-positive solid tumours, when treatment options not targeting RET provide limited clinical benefit, or have been exhausted.	NO REIMBURSEMENT ESMO
Amivantamab	Amivantamab is indicated: - in combination with lazertinib for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations. - in combination with carboplatin and pemetrexed for the treatment of adult patients with advanced NSCLC with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI). - in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with advanced NSCLC with activating EGFR Exon 20 insertion mutations. - as monotherapy for treatment of adult patients with advanced NSCLC with activating EGFR Exon 20 insertion mutations, after failure of platinum-based therapy.	NO REIMBURSEMENT ESMO
Tepotinib	Tepotinib as monotherapy is indicated for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harbouring alterations leading to mesenchymal-epithelial transition factor gene exon 14 (METex14) skipping, who require systemic therapy following prior treatment with immunotherapy and/or platinum-based chemotherapy.	NO REIMBURSEMENT ESMO
Capmatinib	Capmatinib as monotherapy is indicated for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harbouring alterations leading to mesenchymal-epithelial transition factor gene exon 14 (METex14) skipping, who require systemic therapy following prior treatment with immunotherapy and/or platinum-based chemotherapy.	NO REIMBURSEMENT ESMO

Trastuzumab deruxtecan	Trastuzumab Deruxtecan as monotherapy is indicated for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) whose tumours have an activating HER2 (ERBB2) mutation and who require systemic therapy following platinum-based chemotherapy with or without immunotherapy.	NO REIMBURSEMENT ESMO
Adagrasib	Adagrasib as monotherapy is indicated for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with KRAS G12C mutation and disease progression after at least one prior systemic therapy.	NO REIMBURSEMENT ESMO
Tislelizumab	Non-small cell lung cancer (NSCLC) Tislelizumab, in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment, is indicated for the treatment of adult patients with resectable NSCLC at high risk of recurrence. Tislelizumab, in combination with pemetrexed and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with non-squamous NSCLC whose tumours have PD-L1 expression on ≥50% of tumour cells with no EGFR or ALK positive mutations and who have: • locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or • metastatic NSCLC. Tislelizumab, in combination with carboplatin and either paclitaxel or nab-paclitaxel, is indicated for the first-line treatment of adult patients with squamous NSCLC who have: • locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or • metastatic NSCLC. Tislelizumab as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC after prior platinum-based therapy. Patients with EGFR mutant or ALK positive NSCLC should also have received targeted therapies before receiving tislelizumab. Small Cell Lung Cancer (SCLC) Tislelizumab, in combination with etoposide and platinum chemotherapy, is indicated for the first-line treatment of adult patients with extensive-stage SCLC.	NO REIMBURSEMENT ESMO
Sugemalimab	Sugemalimab in combination with platinum-based chemotherapy is indicated for the first-line treatment of adults with metastatic non-small-cell lung cancer (NSCLC) with no sensitising EGFR mutations, or ALK, ROS1 or RET genomic tumour aberrations.	NO REIMBURSEMENT ESMO
Binimetinib	Non-small cell lung cancer (NSCLC) Binimetinib in combination with encorafenib is indicated for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600E mutation.	NO REIMBURSEMENT ESMO

Encorafenib	Non-small cell lung cancer (NSCLC) Encorafenib in combination with binimetinib is indicated for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600E mutation.	NO REIMBURSEMENT ESMO
Repotrectinib	Repotrectinib as monotherapy is indicated for the treatment of adult patients with ROS1-positive advanced non-small cell lung cancer (NSCLC). Repotrectinib as monotherapy is indicated for the treatment of adult and paediatric patients 12 years of age and older with advanced solid tumours expressing a NTRK gene fusion, and - who have received a prior NTRK inhibitor, or - have not received a prior NTRK inhibitor and treatment options not targeting NTRK provide limited clinical benefit, or have been exhausted.	NO REIMBURSEMENT ESMO
Lazertinib	Lazertinib n combination with amivantamab is indicated for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions or exon 21 L858R substitution mutations.	NO REIMBURSEMENT ESMO
Nab-paclitaxel	Nab-Paclitaxel in combination with carboplatin is indicated for the first-line treatment of non-small cell lung cancer in adult patients who are not candidates for potentially curative surgery and/or radiation therapy.	REIMBURSEMENT WITH RESTRICTIONS ESMO
Nivolumab	Nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy is indicated for the first-line treatment of metastatic non-small cell lung cancer in adults whose tumours have no sensitising EGFR mutation or ALK translocation. Nivolumab as monotherapy is indicated for the treatment of locally advanced or metastatic non-small cell lung cancer after prior chemotherapy in adults. Nivolumab in combination with platinum-based chemotherapy is indicated for the neoadjuvant treatment of resectable non-small cell lung cancer at high risk of recurrence in adult patients whose tumours have PD-L1 expression ≥ 1%.	REIMBURSEMENT WITH RESTRICTIONS ESMO

Pembrolizumab	Pembrolizumab, in combination with platinum -containing chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment, is indicated for the treatment of resectable non-small cell lung carcinoma at high risk of recurrence in adults. Pembrolizumab as monotherapy is indicated for the adjuvant treatment of adults with non -small cell lung carcinoma who are at high risk of recurrence following complete resection and platinum-based chemotherapy. Pembrolizumab as monotherapy is indicated for the first-line treatment of metastatic non-small cell lung carcinoma in adults whose tumours express PD-L1 with a ≥ 50% tumour proportion score (TPS) with no EGFR or ALK positive tumour mutations. Pembrolizumab, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of metastatic non-squamous non-small cell lung carcinoma in adults whose tumours have no EGFR or ALK positive mutations. Pembrolizumab, in combination with carboplatin and either paclitaxel or nab-paclitaxel, is indicated for the first-line treatment of metastatic squamous non-small cell lung carcinoma in adults. Pembrolizumab as monotherapy is indicated for the treatment of locally advanced or metastatic non-small cell lung carcinoma in adults whose tumours express PD-L1 with a ≥ 1% TPS and who have received at least one prior chemotherapy regimen. Patients with EGFR or ALK positive tumour mutations should also have received targeted therapy before receiving Pembrolizumab.	REIMBURSEMENT WITH RESTRICTIONS ESMO

Atezolizumab	Early-stage non-small cell lung cancer (NSCLC) Atezolizumab as monotherapy is indicated as adjuvant treatment following complete resection and platinum-based chemotherapy for adult patients with early-stage non-small cell lung cancer (NSCLC) with a high risk of recurrence whose tumours have PD-L1 expression on ≥ 50% of tumour cells (TC) and who do not have EGFR mutant or ALK-positive NSCLC. Advanced NSCLC Atezolizumab, in combination with bevacizumab, paclitaxel and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous NSCLC. In patients with EGFR mutant or ALK-positive NSCLC, Atezolizumab, in combination with bevacizumab, paclitaxel and carboplatin, is indicated only after failure of appropriate targeted therapies. Atezolizumab, in combination with nab-paclitaxel and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous NSCLC who do not have EGFR mutant or ALK-positive NSCLC. Atezolizumab as monotherapy is indicated for the first-line treatment of adult patients with metastatic NSCLC whose tumours have a PD-L1 expression ≥ 50% TC or ≥ 10% tumour-infiltrating immune cells (IC) and who do not have EGFR mutant or ALK-positive NSCLC. Atezolizumab as monotherapy is indicated for the first-line treatment of adult patients with advanced NSCLC who are ineligible for platinum-based therapy. Atezolizumab as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC after prior chemotherapy. Patients with EGFR mutant or ALK-positive NSCLC should also have received targeted therapies before receiving Atezolizumab. Small cell lung cancer (SCLC) Atezolizumab, in combination with carboplatin and etoposide, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).	 REIMBURSEMENT WITH RESTRICTIONS  ESMO

Durvalumab	Non-Small Cell Lung Cancer (NSCLC) Durvalumab combination with platinum-based chemotherapy as neoadjuvant treatment, followed by Durvalumab as monotherapy as adjuvant treatment, is indicated for the treatment of adults with resectable NSCLC at high risk of recurrence and no EGFR mutations or ALK rearrangements. Durvalumab as monotherapy is indicated for the treatment of locally advanced, unresectablenon-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on ≥1% of tumour cells and whose disease has not progressed following platinum-based chemoradiation therapy. Durvalumab in combination with tremelimumab and platinum-based chemotherapy is indicated for the first-line treatment of adults with metastatic NSCLC with no sensitising EGFR mutations or ALK positive mutations. Small Cell Lung Cancer (SCLC) Durvalumab as monotherapy is indicated for the treatment of adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy. Durvalumab in combination with etoposide and either carboplatin or cisplatin is indicated for the first-line treatment of adults with extensive-stage small cell lung cancer (ES-SCLC).	REIMBURSEMENT WITH RESTRICTIONS ESMO
Brigatinib	Brigatinib is indicated as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor. Brigatinib is indicated as monotherapy for the treatment of adult patients with ALK-positive advanced NSCLC previously treated with crizotinib.	REIMBURSEMENT WITH RESTRICTIONS ESMO
Entrectinib	Entrectinib as monotherapy is indicated for the treatment of adult and paediatric patients 12 years of age and older with solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, - who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and - who have not received a prior NTRK inhibitor - who have no satisfactory treatment options. Entrectinib as monotherapy is indicated for the treatment of adult patients with ROS1-positive, advanced non-small cell lung cancer (NSCLC) not previously treated with ROS1 inhibitors.	REIMBURSEMENT WITH RESTRICTIONS ESMO
Ipilimumab	Ipilimumab in combination with nivolumab and 2 cycles of platinum-based chemotherapy is indicated for the first-line treatment of metastatic non-small cell lung cancer in adults whose tumours have no sensitising EGFR mutation or ALK translocation.	REIMBURSEMENT WITH RESTRICTIONS ESMO

Cemiplimab	Cemiplimab as monotherapy is indicated for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 aberrations, who have: - locally advanced NSCLC who are not candidates for definitive chemoradiation, or - metastatic NSCLC. Cemiplimab in combination with platinum-based chemotherapy is indicated for the first-line treatment of adult patients with NSCLC expressing PD-L1 (in ≥ 1% tumour cells), with no EGFR, ALK or ROS1 aberrations, who have: - locally advanced NSCLC who are not candidates for definitive chemoradiation, or - metastatic NSCLC.	REIMBURSEMENT WITH RESTRICTIONS ESMO
Sotorasib	Sotorasib as monotherapy is indicated for the treatment of adults with advanced non-small cell lung cancer (NSCLC) with KRAS G12C mutation and who have progressed after at least one prior line of systemic therapy.	REIMBURSEMENT WITH RESTRICTIONS ESMO
Tremelimumab	Tremelimumab in combination with durvalumab and platinum-based chemotherapy is indicated for the first-line treatment of adults with metastatic non-small cell lung cancer (NSCLC) with no sensitising EGFR mutationsor ALK positive mutations.	REIMBURSEMENT WITH RESTRICTIONS ESMO
Crizotinib	Crizotinib as monotherapy is indicated for: - The first-line treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC), - The treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC), - The treatment of adults with ROS1-positive advanced non-small cell lung cancer (NSCLC).	FULL REIMBURSEMENT ESMO
Afatinib	Afatinib as monotherapy is indicated for the treatment of: - Epidermal Growth Factor Receptor (EGFR) TKI-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s); - Adult patients with locally advanced or metastatic NSCLC of squamous histology progressing on or after platinum-based chemotherapy.	FULL REIMBURSEMENT ESMO
Nintedanib	Nintedanib is indicated in combination with docetaxel for the treatment of adult patients with locally advanced, metastatic or locally recurrent non-small cell lung cancer (NSCLC) of adenocarcinoma tumour histology after first-line chemotherapy.	FULL REIMBURSEMENT ESMO

Osimertinib	Osimertinib as monotherapy is indicated for: - the adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIA non small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. - the treatment of adult patients with locally advanced, unresectable NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following platinum-based chemoradiation therapy. - the first-line treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR mutations. - the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC. Osimertinib is indicated in combination with: - pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with advanced NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.	FULL REIMBURSEMENT ESMO
Alectinib	Adjuvant treatment of resected non-small cell lung cancer (NSCLC) Alecensa as monotherapy is indicated as adjuvant treatment following complete tumour resection for adult patients with ALK-positive NSCLC at high risk of recurrence. Treatment of advanced NSCLC Alectinib as monotherapy is indicated for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC). Alectinib as monotherapy is indicated for the treatment of adult patients with ALK-positive advanced NSCLC previously treated with crizotinib.	FULL REIMBURSEMENT ESMO
Lorlatinib	Lorlatinib as monotherapy is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor. Lorlatinib as monotherapy is indicated for the treatment of adult patients with ALK-positive advanced NSCLC whose disease has progressed after: - alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy; or - crizotinib and at least one other ALK TKI.	FULL REIMBURSEMENT ESMO
Larotrectinib	Larotrectinib as monotherapy is indicated for the treatment of adult and paediatric patients with solid tumours that display a Neurotrophic Tyrosine Receptor Kinase (NTRK) gene fusion, - who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and - who have no satisfactory treatment options.	FULL REIMBURSEMENT ESMO