2024

台灣肺癌藥物治療共識

共同編撰 | 台灣胸腔暨重症加護醫學會
台灣臨床腫瘤醫學會
中華民國癌症醫學會
台灣免疫腫瘤學會
台灣肺癌學會
台灣胸腔外科醫學會

編撰委員

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分組	組長	組員					
		台灣胸腔暨重症加護醫學會	台灣肺癌學會	台灣臨床腫瘤醫學會	中華民國癌症醫學會	台灣免疫腫瘤學會	台灣胸腔外科醫學會
小細胞肺癌	何肇基	蔡鎮良 蕭世欣	江起陸 賴建豪	施慧瑄 朱逸羣	官鋒澤 徐偉勛	吳銘芳 張境夫	–
鱗狀細胞癌	賴俊良	張時杰 楊宗穎	蘇健 羅永鴻	楊志仁 徐稟智	吳教恩 廖斌志	謝燿宇	–
非鱗狀細胞癌有驅動基因	夏德椿	蘇健 郭志熙	黃俊耀 廖唯昱	徐培菘 何明霖	張家崙 李純慧	王智亮 張家崙	–
非鱗狀細胞癌無驅動基因	張文震	林建中 涂智彥	郭志熙 趙恒勝	林旻希 潘奕宏	謝燿宇 徐偉勛	吳教恩	–
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Levels of evidence

I. Evidence from at least one large randomized, controlled trial of good methodological quality (low potential for bias) or meta-analyses of well-conducted randomized trials without heterogeneity

II. Small randomized trials or large randomized trials with a suspicion of bias (low methodological quality) or meta-analyses of such trials or of trials with demonstrated heterogeneity

III. Prospective cohort studies

IV. Retrospective cohort studies of case–control studies

V. Studies without control group, case reports, experts' opinions

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Advanced non-squamous cell carcinoma with actionable oncogenic drivers

[#]Not Taiwan FDA approved.

EGFR mutation

▶ First-line treatment

■ Sensitizing *EGFR* mutation

- Osimertinib is preferred (**Category I**) [1].
- Osimertinib and pemetrexed with (cisplatin or carboplatin), gefitinib, erlotinib, afatinib, or dacomitinib are also recommended (**Category I**) [2-6].
- Erlotinib with bevacizumab or erlotinib with ramucirumab represents a front-line treatment option (**Category II**) [7, 8].

■ *EGFR* S768I, L861Q, and/or G719X mutations

- Afatinib is preferred (**Category II**) [3].
- Gefitinib, erlotinib, dacomitinib, or osimertinib are also recommended (**Category II**) [4-6, 9].

▶ Second-line treatment

- Progression on afatinib, erlotinib, dacomitinib, or gefitinib should be tested for the presence of the *EGFR* exon 20 T790M mutation (tissue biopsy and/or liquid biopsy).
- Osimertinib is the standard therapy for $EGFR^{T790M}$ positive after first-line EGFR-TKI (**Category I**) [10].
- Amivantamab-vmjw with carboplatin and pemetrexed is preferred after progression on osimertinib (**Category I**) [11].
- Systemic therapy including platinum-based doublet chemotherapy is the standard therapy for patients whose tumor is tested $EGFR^{T790M}$ negative.
- Combination of atezolizumab and bevacizumab with carboplatin and paclitaxel might be considered (**Category IV**) [12].

EGFR exon 20 insertion

▶ First-line treatment

- Amivantamab-vmjw with carboplatin and pemetrexed is preferred (**Category I**) [13].

- *EGFR*-A763_Y764insFQEA is sensitive to first-, second-, and third-generation EGFR TKIs [14].
- Systemic therapy including platinum-based doublet chemotherapy is also recommended.

▶ Second-line treatment

- Amivantamab-vmjw is preferred after progression on systemic therapy including platinum-based doublet chemotherapy (**Category II**) [15].

ALK rearrangement

▶ First-line treatment

- Alectinib, brigatinib or lorlatinib are preferred (**Category I**) [16-18].
- Ceritinib is recommended (**Category I**) [19].
- Crizotinib is also recommended (**Category I**) [20].

▶ Second-line treatment

- Ceritinib, alectinib, brigatinib or lorlatinib are preferred after progression on crizotinib or intolerant to crizotinib (**Category I**) [19, 21-23].
- Lorlatinib is recommended in patients who progress after a second-generation ALK TKIs (**Category II**) [23].
- Systemic therapy including platinum-based doublet chemotherapy should be considered if the next-generation ALK inhibitors are not available.
- Combination of atezolizumab and bevacizumab with carboplatin and paclitaxel might be considered (**Category IV**) [12].

ROS1 rearrangement

▶ First-line treatment

- Entrectinib, crizotinib or repotrectinib[#] are preferred (**Category II**) [24-26].
- Ceritinib is also recommended (**Category III**) [27].

▶ Second-line treatment

- Repotrectinib[#] (if not previously given) or lorlatinib are preferred (**Category III**) [28, 29].
- Entrectinib is recommended in patients who progress after crizotinib or ceritinib (**Category III**) [24].
- Systemic therapy including platinum-based doublet chemotherapy if the next-generation ROS-1 inhibitors are not available.

BRAF^{V600E} mutation

▶ First-line treatment

- Dabrafenib/trametinib or encorafenib/binimetinib[#] are preferred (**Category II**) [30, 31].

▶ Second-line treatment

- Systemic therapy including platinum-based doublet chemotherapy is recommended.

RET rearrangement

▶ First-line treatment

- Selpercatinib or pralsetinib are preferred (**Category II**) [32, 33].

▶ Second-line treatment

- Systemic therapy including platinum-based doublet chemotherapy is recommended.

NTRK1/2/3 gene fusion

▶ First-line treatment

- Larotrectinib, entrectinib or repotrectinib[#] are preferred (**Category II**) [34-36].

▶ Second-line treatment

- Repotrectinib[#] (if not previously given) is recommended (**Category II**) [36].
- Systemic therapy including platinum-based doublet chemotherapy is also recommended.

*MET*ex14 skipping mutation

▶ First-line treatment

- Capmatinib or tepotinib are preferred (**Category II**) [37, 38].
- Crizotinib is also recommended (**Category II**) [39].

▶ Second-line treatment

- Systemic therapy including platinum-based doublet chemotherapy is recommended.

KRAS^{G12C} mutation

▶ First-line treatment

- Systemic therapy including platinum-based doublet chemotherapy and/or immunotherapy is recommended depending on PD-L1 expression.

▶ Second-line treatment

- Sotorasib or adagrasib[#] are recommended (**Category II**) [40, 41].

ERBB2 (*HER2*) mutation

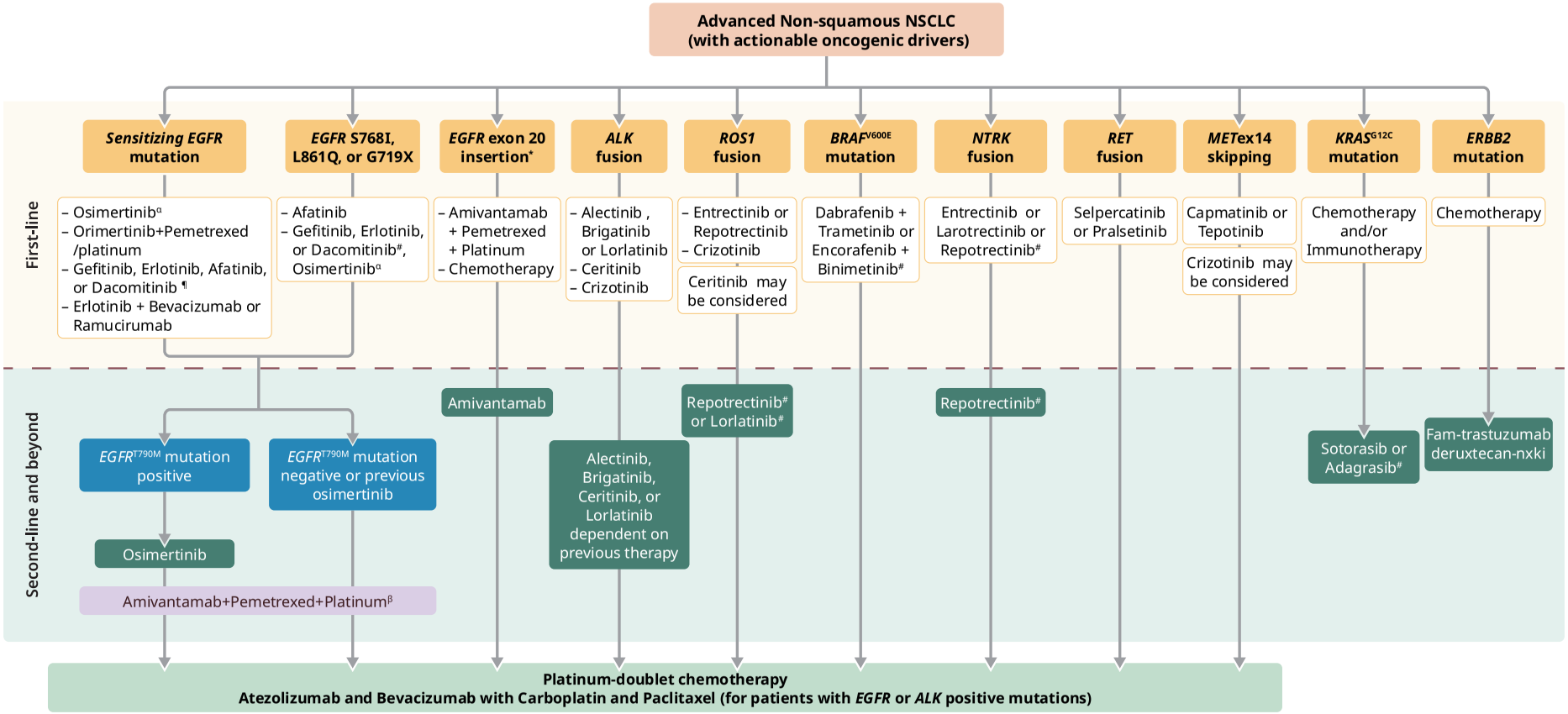
▶ First-line treatment

- Systemic therapy including platinum-based doublet chemotherapy is recommended.

▶ Second-line treatment

- Fam-trastuzumab deruxtecan-nxki is recommended (**Category II**) [42] .

Advanced Non-squamous NSCLC with Actionable Oncogenic Drivers



[¶]Dacomitinib: No brain metastasis data; [α]Osimertinib: favor patients with brain metastasis or leptomeningeal carcinomatosis; *_EGFR_-A763_Y764insFQEA: Sensitive to first-, second-, and third-generation EGFR TKIs.
PS: Drug sequence by time to market; [β]only for after progression on osimertinib; [#]Not Taiwan FDA approved.

Advanced non-squamous cell carcinoma without actionable oncogenic drivers

[#]Not Taiwan FDA approved.

Immunotherapy should be considered for all non-squamous NSCLC patients without actionable oncogene drivers. In the patients unfit for PD-1 or PD-L1 inhibitors,[†] chemotherapy should be considered.

[†]**Unfit to the treatment of PD-1 or PD-L1 inhibitor** [43, 44]

- Active or previously documented autoimmune disease and/or current use of immunosuppressive agents.
- Presence of an oncogene (eg, *EGFR* [exon 19 deletions, p.L858R point mutation in exon 21], *ALK*, *ROS1* or *RET* rearrangements), which would predict lack of benefit [45, 46].
- If progression on PD-1/PD-L1 inhibitor, switching to another using a PD-1/PD-L1 inhibitor is not recommended.

First-line treatment

■ PD-L1 ≥ 50%

- Pembrolizumab, atezolizumab, or combination pembrolizumab with pemetrexed and platinum, is preferred (**Category I**) [47-49].
- Atezolizumab in combination with bevacizumab, paclitaxel and carboplatin, combination atezolizumab with carboplatin and nab-paclitaxel, combination nivolumab and Ipilimumab with pemetrexed and platinum, or nivolumab in combination with bevacizumab, paclitaxel and carboplatin is also recommended (**Category I**) [50-53]. The other option is tremelimumab-actl and durvalumab with carboplatin and albumin-bound paclitaxel or tremelimumab-actl and durvalumab with (carboplatin or cisplatin) and gemcitabine (**Category II**) [54].[#]
- Combination nivolumab and ipilimumab represents a front-line treatment option (**Category I**) [55].

■ PD-L1 ≥ 1%–49%

- Pembrolizumab with pemetrexed and platinum is preferred (**Category I**) [49].
- Atezolizumab in combination with bevacizumab, paclitaxel and carboplatin, combination atezolizumab with carboplatin and nab-paclitaxel, combination nivolumab and ipilimumab with pemetrexed and platinum, or nivolumab in combination with bevacizumab, paclitaxel and carboplatin is also recommended (**Category I**) [50-53].
- Combination nivolumab and ipilimumab represents a front-line treatment option

(**Category I**) [55]. The other option is pembrolizumab, especially for patients who are not suitable for chemotherapy (**Category I**) [56]. The other option is tremelimumab-actl and durvalumab with carboplatin and albumin-bound paclitaxel or tremelimumab-actl and durvalumab with (carboplatin or cisplatin) and gemcitabine (**category II**) [54].#

■ PD-L1 < 1%

- Pembrolizumab with pemetrexed and platinum is preferred (**Category I**) [49].
- Atezolizumab in combination with bevacizumab, paclitaxel and carboplatin, combination atezolizumab with carboplatin and nab-paclitaxel, or combination nivolumab and ipilimumab with pemetrexed and platinum are also recommended (**Category I**) [50-52].
- The other option is tremelimumab-actl and durvalumab with carboplatin and albumin-bound paclitaxel or tremelimumab-actl and durvalumab with (carboplatin or cisplatin) and gemcitabine (**Category II**) [54].#
- Combination nivolumab and ipilimumab# is also effective in the post-hoc analysis (**Category II**) [55].

■ Contraindications to immunotherapy or immunotherapy are not available

- Maximum six cycles of platinum-based doublet chemotherapy is suggested (**Category I**) [57].
- Pemetrexed is preferred to gemcitabine or docetaxel for patients with non-squamous tumors (**Category I**) [58, 59].
- Less toxic maintenance monotherapy should be considered, and pemetrexed is preferred (**Category I**) [60].
- Combination bevacizumab with paclitaxel and carboplatin, or combination bevacizumab with pemetrexed and platinum may be offered in the absence of contraindications (**Category I**) [61-63].

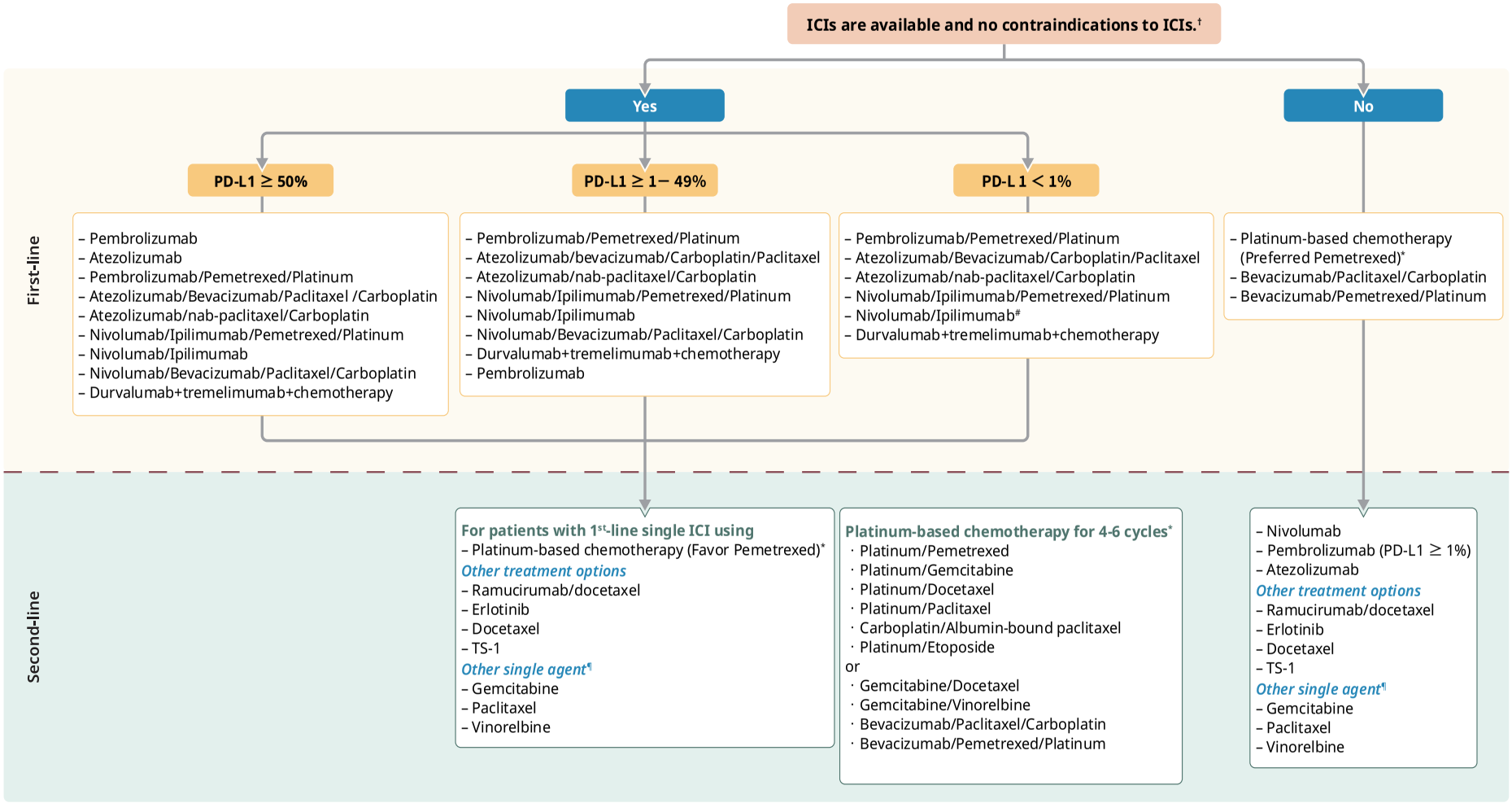
Second-line treatment

- For patients with progression after first-line immunotherapy (pembrolizumab, atezolizumab, combination of nivolumab and ipilimumab, or cemiplimab-rwlc#), platinum-based doublet chemotherapy is recommended as the second-line treatment option.
- PD-1 and PD-L1 inhibitors (nivolumab and atezolizumab) are the treatment of choice for PD-L1 inhibitor-naive NSCLC in second-line setting, irrespective of PD-L1 expression (**Category I**) [64, 65]. Pembrolizumab is indicated for second-line treatment of lung cancer

with PD-L1 ≥ 1% (**Category I**) [66].

- In patients not suitable for immunotherapy, second-line chemotherapy is recommended.
- Docetaxel with/without Ramucirumab, or TS-1 is a treatment option in NSCLC patients progressing after first-line chemotherapy (**Category I**) [67-69].
- Erlotinib represents a potential second- or third-line treatment option in particular for patients not suitable for immunotherapy or second-line chemotherapy in unknown *EGFR* status or *EGFR*-WT tumors (**Category II**) [70].
- Although the supporting evidence base is limited, the other single agents, including gemcitabine, paclitaxel, or vinorelbine, can be considered as treatment options (**Category II**) [71-75].

Advanced Non-squamous NSCLC without Actionable Oncogenic Drivers



*Maximum six cycles of platinum-based doublets followed by less toxic maintenance monotherapy should be considered (*N Engl J Med 2002; 346:92-98; Lancet. 2009;374:1432-40.*); #Not Taiwan FDA approved.
†Contraindications for treatment with PD-1/PD-L1 inhibitors may include active or previously documented autoimmune disease and/or current use of immunosuppressive agents, or presence of an oncogene (ie, *EGFR* exon 19 deletion or L858R, *ALK*, *ROS1* or *RET* rearrangements), which would predict lack of benefit (NCCN guideline) ICI: Immune checkpoint inhibitors; ¶The supporting evidence base is limited.

Advanced squamous cell carcinoma without actionable oncogenic drivers

[#]Not Taiwan FDA approved.

Immunotherapy should be considered for all squamous NSCLC patients without actionable oncogene drivers. In the patients unfit for PD-1 or PD-L1 inhibitors,[†] chemotherapy should be considered. Molecular testing for the identification of driver mutations should be considered for patients with lung squamous cell carcinoma, especially for never-/light-smokers. Targeted therapies are recommended if actionable mutations are detected.

[†]**Unfit to the treatment of PD-1 or PD-L1 inhibitor** [43, 44]

- Active or previously documented autoimmune disease and/or current use of immunosuppressive agents.
- Presence of some oncogenes (eg, *EGFR*, *ALK*, *ROS1* or *RET* rearrangements), which would predict lack of benefit [45, 46].
- If progression on PD-1/PD-L1 inhibitor, switching to another using a PD-1/PD-L1 inhibitor is not recommended.

First-line treatment

■ PD-L1 ≥ 50%

- Pembrolizumab, atezolizumab, or combination pembrolizumab with paclitaxel or albumin bound paclitaxel and carboplatin are preferred (**Category I**) [47, 48, 76].
- Combination nivolumab and Ipilimumab with paclitaxel and carboplatin is also recommended (**Category I**) [52]. The other option is tremelimumab-actl and durvalumab with carboplatin and albumin-bound paclitaxel or tremelimumab-actl and durvalumab with (carboplatin or cisplatin) and gemcitabine (**Category II**) [54].[#]
- Combination nivolumab and Ipilimumab represent a front-line treatment option (**Category I**) [55].

■ PD-L1 ≥ 1%–49%

- Pembrolizumab with paclitaxel or albumin bound paclitaxel and carboplatin is preferred (**Category I**) [76].
- Combination nivolumab and Ipilimumab with paclitaxel and carboplatin is also recommended (**Category I**) [52]. The other option is tremelimumab-actl and durvalumab with carboplatin and albumin-bound paclitaxel or tremelimumab-actl and durvalumab with (carboplatin or cisplatin) and gemcitabine (**Category II**) [54].[#]
- Combination nivolumab and ipilimumab represent a front-line treatment option (**Category**

I) [55]. The other option is pembrolizumab, especially for patients who are not suitable for chemotherapy (**Category I**) [56].

■ PD-L1 < 1%

- Pembrolizumab with paclitaxel or albumin bound paclitaxel and carboplatin is preferred (**Category I**) [76].
- Combination nivolumab and Ipilimumab with paclitaxel and carboplatin is also recommended (**Category I**) [52].
- The other option is tremelimumab-actl and durvalumab with carboplatin and albumin-bound paclitaxel or tremelimumab-actl and durvalumab with (carboplatin or cisplatin) and gemcitabine (**Category II**) [54].#
- Combination nivolumab and ipilimumab is also effective in the post-hoc analysis although it is not approved by TFDA (**Category II**) [55].#

■ Contraindications to immunotherapy or immunotherapy are not available

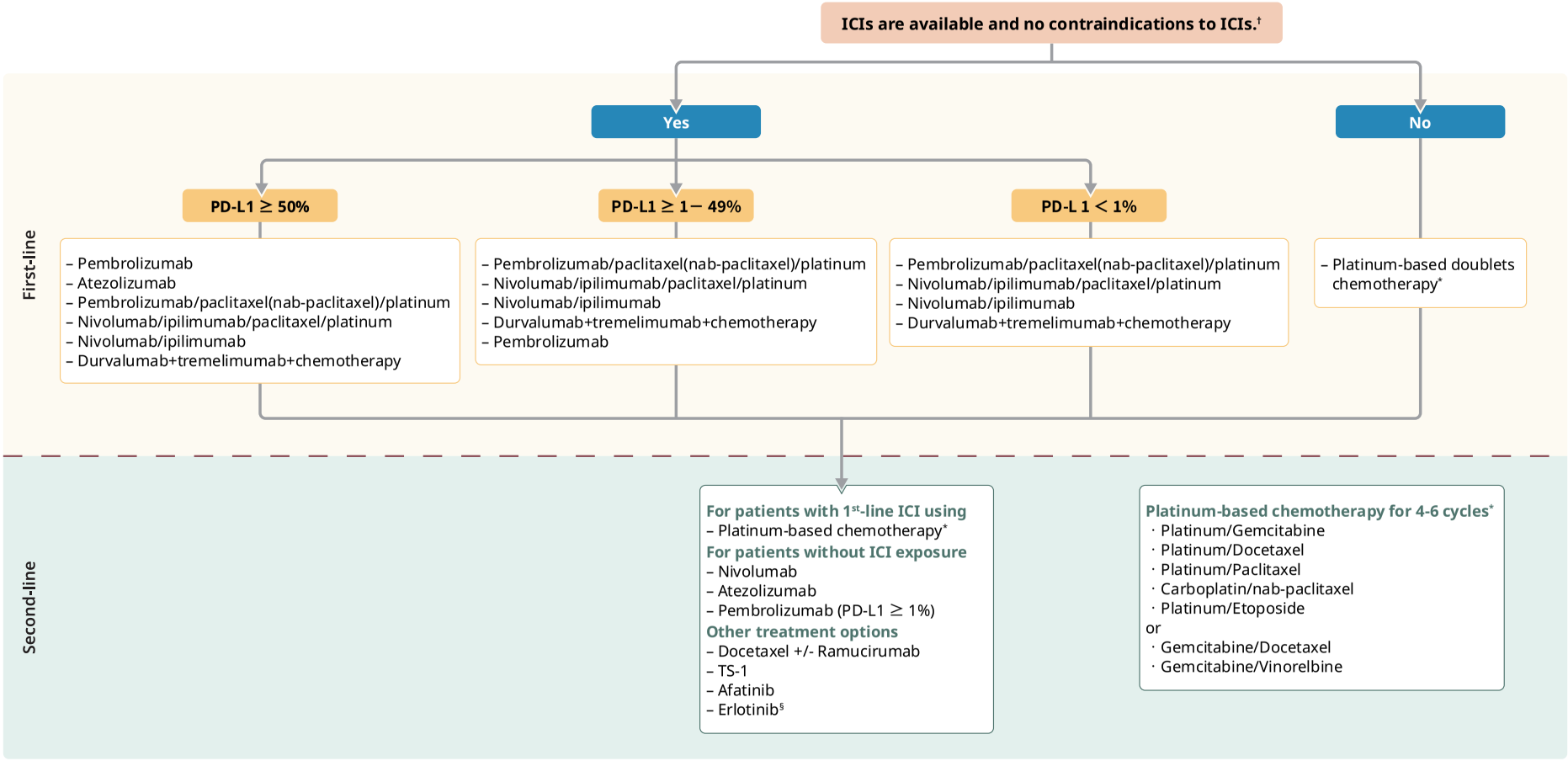
- Maximum six cycles of platinum-based doublet chemotherapy is suggested (**Category I**) [57].*

  * Pemetrexed is not recommended for the treatment of squamous cell carcinoma [58].

Second-line treatment

- For patients with progression after first-line immunotherapy (pembrolizumab, atezolizumab, combination of nivolumab and ipilimumab), platinum-based chemotherapy is recommended as the second-line treatment option.
- PD-L1 and PD-1 inhibitors (nivolumab and atezolizumab) are the treatment of choice for PD-L1 inhibitor-naive NSCLC in second-line setting, irrespective of PD-L1 expression (**Category I**) [64, 65, 77]. Pembrolizumab is indicated for second-line treatment of lung cancer with PD-L1 ≥ 1% (**Category I**) [66].
- In patients not suitable for immunotherapy, second-line chemotherapy is recommended.
- Docetaxel+/-Ramucirumab, or TS-1 is a treatment option in NSCLC patients progressing after first-line chemotherapy (**Category I**) [67-69].
- Afatinib is approved for the second-line treatment lung squamous cell carcinoma irrespective of the *EGFR* mutation status (**Category I**) [78]. Erlotinib is only reimbursed as the third-line treatment of squamous cell carcinoma (**Category II**) [70].

Advanced Squamous Cell Carcinoma



*Maximum six cycles of platinum-based doublets chemotherapy is suggested (*N Engl J Med 2002; 346:92-98*)
†Contraindications for treatment with PD-1/PD-L1 inhibitors may include active or previously documented autoimmune disease and/or current use of immunosuppressive agents, or presence of some oncogenes, which would predict lack of benefit (NCCN guideline).
§ Erlotinib is reimbursed as the third-line treatment by Taiwan NHI.

Small cell lung cancer

[#]Not Taiwan FDA approved.

Limited-stage SCLC

1. Management of limited-stage SCLC should be discussed in a multidisciplinary committee.
2. Clinical stage I-IIA (T1-2, N0, M0) should consider pathological mediastinal staging, then Lobectomy and mediastinal lymph node dissection or sampling should be considered in pathologic mediastinal staging negative.
3. Limited stage IIB-IIIC (T3-4, N0, M0; T1-4, N1-3, M0) with good performance status (ECOG 0-2), systemic therapy with concurrent radiotherapy should be considered (**Category I**). Poor performance status (ECOG 3-4), systemic therapy with/without radiotherapy (concurrent or sequential) should be considered.

■ Primary or adjuvant therapy for limited-stage SCLC

▶ Preferred regimens

- Cisplatin and etoposide are preferred (**Category I**) [79].
- Carboplatin and etoposide are also recommended (**Category I**) [79].
- Adjuvant therapy with durvalumab after concurrent or sequential chemoradiotherapy for 24 month is preferred (**Category I**) [80].

Extensive-stage SCLC

■ Primary therapy for extensive-stage SCLC

▶ Preferred regimens

- Carboplatin and etoposide and atezolizumab every 21 days x 4 cycles followed by maintenance atezolizumab every 21 days should be considered (**Category I**) [81].
- Carboplatin or Cisplatin and etoposide and durvalumab every 21 days x 4 cycles followed by maintenance durvalumab every 28 days should be considered (**Category I**) [82].

▶ Other recommended regimens

- Carboplatin and etoposide for 4–6 cycles [83].
- Cisplatin and etoposide for 4–6 cycles [84-86].

■ Relapse SCLC or second-line therapy

▶ Preferred regimens

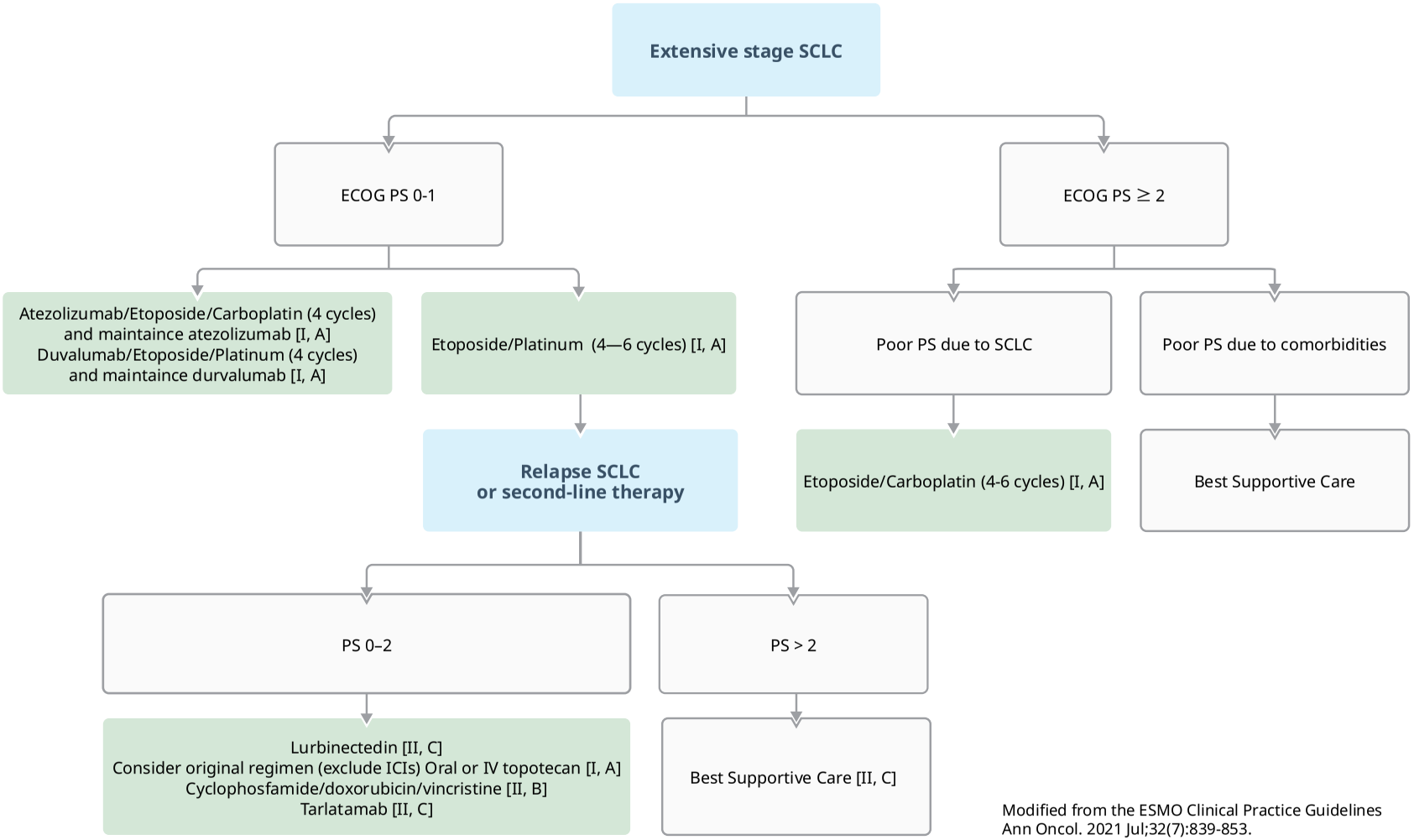
- Lurbinectedin [87].
- Topotecan PO or IV [88].
- The original regimen, excluding ICIs, is also considered [89].*
- Tarlatamab [90].#

** Rechallenging with the original regimen or similar platinum-based regimens recommended if there has been a chemotherapy-free interval (CTFI) of more than 6 months and may be considered if there has been a CTFI of at least 3 to 6 months.*

▶ Other recommended regimens

- TFDA Approved
  - ✓ Cyclophosphamide/doxorubicin/vincristine (CAV) [88].
  - ✓ Oral etoposide [91, 92].
- No TFDA Approved
  - ✓ Paclitaxel [93, 94].
  - ✓ Docetaxel [95].
  - ✓ Irinotecan [96].
  - ✓ Temozolomide [97, 98].
  - ✓ Vinorelbine [99, 100].
  - ✓ Gemcitabine [101, 102].
  - ✓ Nivolumab [103, 104].
  - ✓ Bendamustine [105].

Small Cell Lung Carcinoma



Modified from the ESMO Clinical Practice Guidelines
Ann Oncol. 2021 Jul;32(7):839-853.

Perioperative Systemic Treatment in Stage I-III NSCLC

Systemic treatment should be initiated after a surgical consultation or a discussion by a multidisciplinary team.

Pre-Surgical Recommendations (Category IIA)

- Pulmonary function tests: It is suggested if not previously completed.
- Bronchoscopy and pathologic mediastinal lymph node evaluations: It is recommended to assess for N2 disease and discuss the appropriateness of surgery within a multidisciplinary team.
- FDG-PET/CT scan and brain MRI with contrast (≥ stage IB): Suggested if not previously performed, prior to thoracic surgical oncology consultation.
- Molecular testing: Suggested for *EGFR* mutations, *ALK* rearrangements, and PD-L1 expression before systemic treatment.

Resected Stage IB to IIIA

■ *EGFR* Mutations: del-19 or L858R

- Adjuvant therapy with osimertinib for 3 years is preferred (**Category I**) [106, 107].
- Chemotherapy: Four cycles of adjuvant chemotherapy are also recommended before osimertinib (**Category I**) [106].

■ Resected Stage II and IIIA (*ALK* Rearrangements)

- Adjuvant therapy with alectinib for 2 years is preferred (**Category I**) [108].

■ Operable Stage II

▶ Adjuvant Treatment

- UFUR for 2 years: for pathological staging T2 (tumor ≥ 3cm) lung adenocarcinoma patients [109].
- Four cycles of adjuvant chemotherapy are recommended (**Category I for stage IIB**) [110].
- Adjuvant atezolizumab (for PD-L1 ≥ 1%)(1200 mg every 21 days; for 16 cycles or 1 year) and pembrolizumab (200 mg every 3 weeks for up to 18 cycles) after chemotherapy are also recommended for patients without sensitizing *EGFR* mutations and *ALK* rearrangement (**Category I**) [111, 112].

▶ Neoadjuvant Treatment

- Neoadjuvant systemic therapy with nivolumab and platinum-doublet chemotherapy every

3 weeks for 3 cycles is recommended for patients without sensitizing *EGFR* mutations and *ALK* rearrangement (**Category I**) [113].

- Neoadjuvant systemic therapy with chemotherapy may be also considered.

▶ Perioperative Treatment

- Pembrolizumab/Durvalumab and platinum-based doublet chemotherapy every 3 weeks for 4 cycles, followed by single-agent pembrolizumab/durvalumab as adjuvant treatment after surgery, is recommended for patients without sensitizing *EGFR* mutations and *ALK* rearrangement (**Category I**) [113, 114].

■ Operable Stage III

▶ Adjuvant Treatment

- Four cycles of adjuvant chemotherapy are recommended (**Category I**) [110].
- Adjuvant atezolizumab (for PD-L1 ≥ 1%)(1200 mg every 21 days; for 16 cycles or 1 year) or pembrolizumab (200 mg every 3 weeks for up to 18 cycles) after chemotherapy is preferred for patients without sensitizing *EGFR* mutations and *ALK* rearrangement (**Category I**) [111, 112].

▶ Neoadjuvant Treatment

- Neoadjuvant systemic therapy with nivolumab and platinum-doublet chemotherapy every 3 weeks for 3 cycles is preferred for patients without sensitizing *EGFR* mutations and *ALK* rearrangement (**Category I**) [113].
- Neoadjuvant systemic therapy with chemotherapy may also be considered.

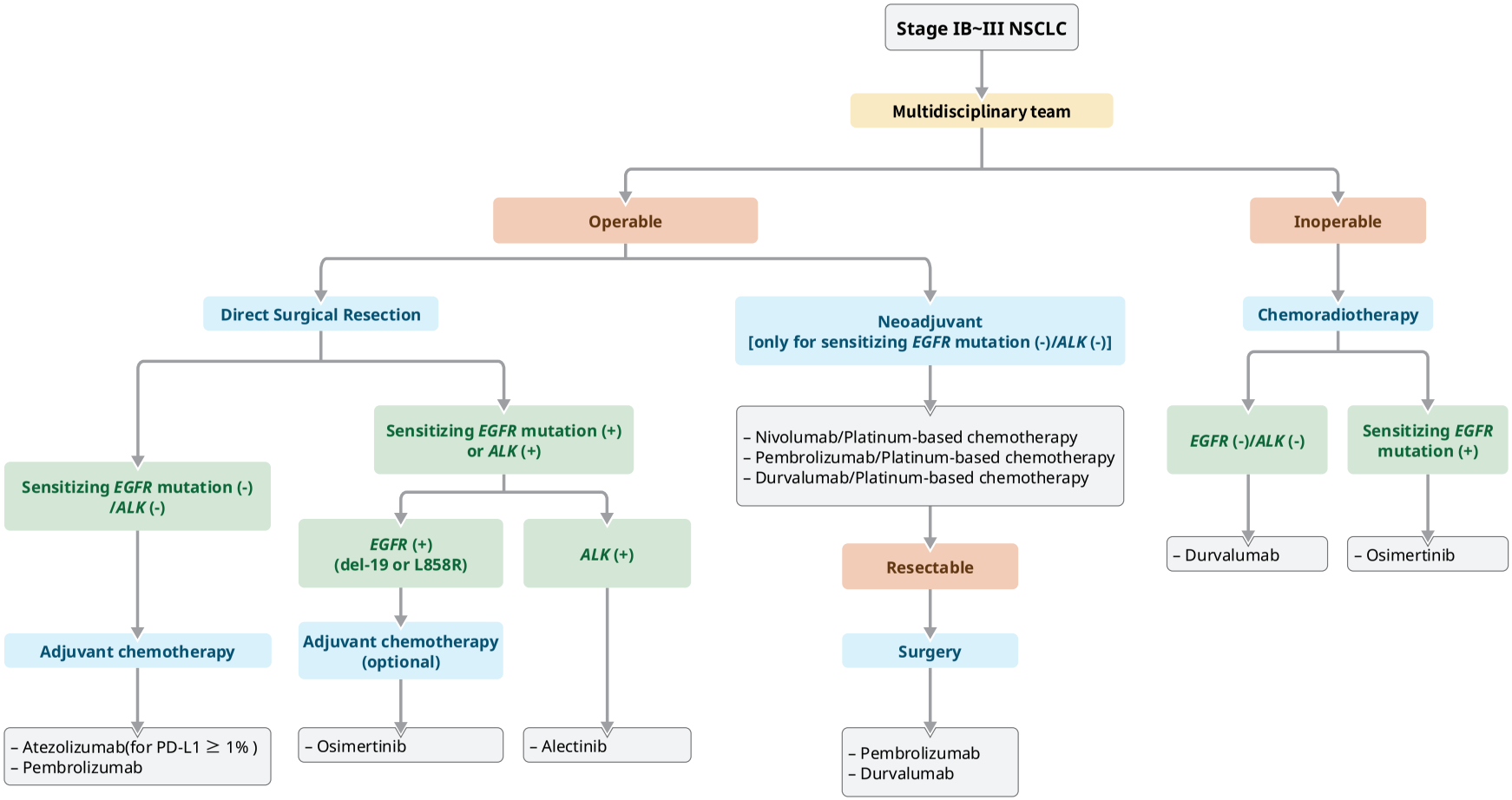
▶ Perioperative Treatment

- Pembrolizumab/Durvalumab and platinum-based doublet chemotherapy every 3 weeks for 4 cycles, followed by single-agent pembrolizumab/durvalumab as adjuvant treatment after surgery, is preferred for patients without sensitizing *EGFR* mutations and *ALK* rearrangement (**Category I**) [113, 114].

Inoperable Stage II-III

- **Consolidation Therapy**: Durvalumab after concurrent or sequential chemoradiotherapy for 1 year is preferred for patients without sensitizing *EGFR* mutations and *ALK* rearrangements (**Category I for Stage III**; **Category IIA for Stage II**) [115-117].
- **Osimertinib**: Recommended until disease progression in cases of *EGFR* exon 19 deletion or L858R mutations (**Category I for Stage III**; **Category IIA for Stage II**) [118].

Perioperative Systemic Treatment in Stage I-III NSCLC



Reference

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