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An ESMO Product

Oncogene-Addicted Metastatic Non-Small-Cell Lung Cancer

ESMO Living Guideline, v1.2 January 2025

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Diagnosis, Pathology and Molecular Biology (1/3)

Summary of recommendations	LoE, GoR
Adequate tissue material for histological diagnosis and molecular testing should be obtained to allow for individual treatment decisions. For recommended methods to obtain tissue, please refer to the ESMO CPG on Non-Oncogene-Addicted mNSCLC (Hendriks, 2023)	IV, A
Pathological diagnosis should be made according to the 2021 WHO classification of lung tumours	IV, A
Specific subtyping of all NSCLCs is necessary for therapeutic decision making and should be carried out wherever possible. IHC stains should be used to reduce the NSCLC-not otherwise specified rate to <10% of cases diagnosed	IV, A
The molecular tests described in the following recommendations are recommended in patients with advanced non-squamous-cell carcinoma and not recommended in patients with a confident diagnosis of squamous-cell carcinoma, except in unusual cases, e.g. young (<50 years) patients, never (<100 cigarettes in a lifetime)/former light smokers (≤15 pack-years, all kinds of tobacco) or long-time ex-smokers (quit smoking >15 years ago, all kinds of tobacco)	IV, A
EGFR mutation status should be determined Test methodology should have adequate coverage of mutations in exons 18-21, including those associated with resistance to some therapies At a minimum, when resources or material are limited, the most common activating mutations (exon 19 deletion, exon 21 L858R point mutation) should be determined	I, A III, A I, A

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Diagnosis, Pathology and Molecular Biology (2/3)

Summary of recommendations	LoE, GoR
The availability of TKIs effective against T790M-mutated recurrent disease makes T790M testing on disease relapse on first- or second-generation EGFR TKIs mandatory	I, A
Testing for *ALK* rearrangements should be carried out	I, A
Detection of the *ALK* translocation by FISH remains a standard, but IHC with high-performance ALK antibodies and validated assays may be used for screening and have been accepted as an equivalent alternative to FISH for ALK testing	III, A
Testing for *ROS1* rearrangements should be carried out Detection of the *ROS1* translocation by FISH remains a standard; IHC may be used as a screening approach	II, A IV, A
BRAF V600 mutation status testing should be carried out	II, A
Testing for *NTRK* rearrangements should be carried out. Screening for *NTRK* rearrangements may use IHC or NGS, with appropriate testing follow-up to validate a positive result	II, A
Testing for *MET* exon 14 skipping mutations, *MET* amplifications, *RET* rearrangements, *KRAS* G12C mutations and *HER2* mutations should be carried out	II, A

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Diagnosis, Pathology and Molecular Biology (3/3)

Summary of recommendations	LoE, GoR
If available, multiplex platforms (NGS) for molecular testing are preferable	III, A
RNA-based NGS is preferred for identifying an expanding range of fusion genes	III, B
Whichever testing modality is used, it is mandatory that adequate internal validation and quality control measures are in place and that laboratories participate in, and perform adequately in, external quality assurance schemes for each biomarker test	III, A
cfDNA (liquid biopsy) can be used to test for oncogenic drivers as well as resistance mutations, but all patients with a negative cfDNA blood test still require tissue biopsy	II, A

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Staging and Risk Assessment (1/2)

Summary of recommendations	LoE, GoR
A complete history including a precise smoking history and comorbidities, weight loss, ECOG PS and physical examination must be recorded	IV, A
Laboratory standard tests including routine haematology, renal and hepatic functions and bone biochemistry tests are required. Other tests (e.g. lipid spectrum and creatine kinase levels) depend on toxicity of the targeted therapy that will be used	IV, A
An electrocardiogram is required if the targeted therapy can cause adverse cardiac events, including rhythmic modifications (e.g. long QT)	IV, A
Contrast-enhanced CT scan of the chest and upper abdomen (including the liver and adrenal glands) should be carried out at diagnosis	IV, A
Imaging of the central nervous system should be considered at diagnosis for all patients with metastatic disease • It is required for patients with neurological symptoms or signs If available, central nervous system imaging with gadolinium-enhanced MRI should be considered for all patients	IV, B IV, A IV, B
If bone metastases are clinically suspected, bone imaging is required	IV, B
Bone scintigraphy, ideally coupled with CT, can be used for detection of bone metastasis FDG–PET–CT is the most sensitive modality in detecting bone metastasis	IV, B III, B

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Staging and Risk Assessment (2/2)

Summary of recommendations	LoE, GoR
FDG–PET–CT and brain imaging are recommended in patients suspected for oligometastatic disease. In the presence of a solitary metastatic site on imaging studies, efforts should be made to obtain a cytological or histological confirmation of stage IV disease	IV, A
For oligometastatic disease, mediastinal disease should be pathologically confirmed if this potentially impacts the treatment plan	IV, A
NSCLC must be staged according to the AJCC/UICC TNM 8th edition staging manual and must be grouped into the stage categories shown in Supplementary Tables S2 and S3	IV, A
Response evaluation is recommended after 8-12 weeks of treatment, using the same radiographic investigation that initially demonstrated the tumour lesions Follow-up with a PET scan is not routinely recommended, due to its relatively low specificity despite a high sensitivity	IV, B IV, C
Measurements and response assessment should follow RECIST v1.1 The clinical relevance of RECIST in evaluating the response remains debatable as patients can derive benefit from continuing the same TKI after RECIST v1.1 progression	IV, A III, A

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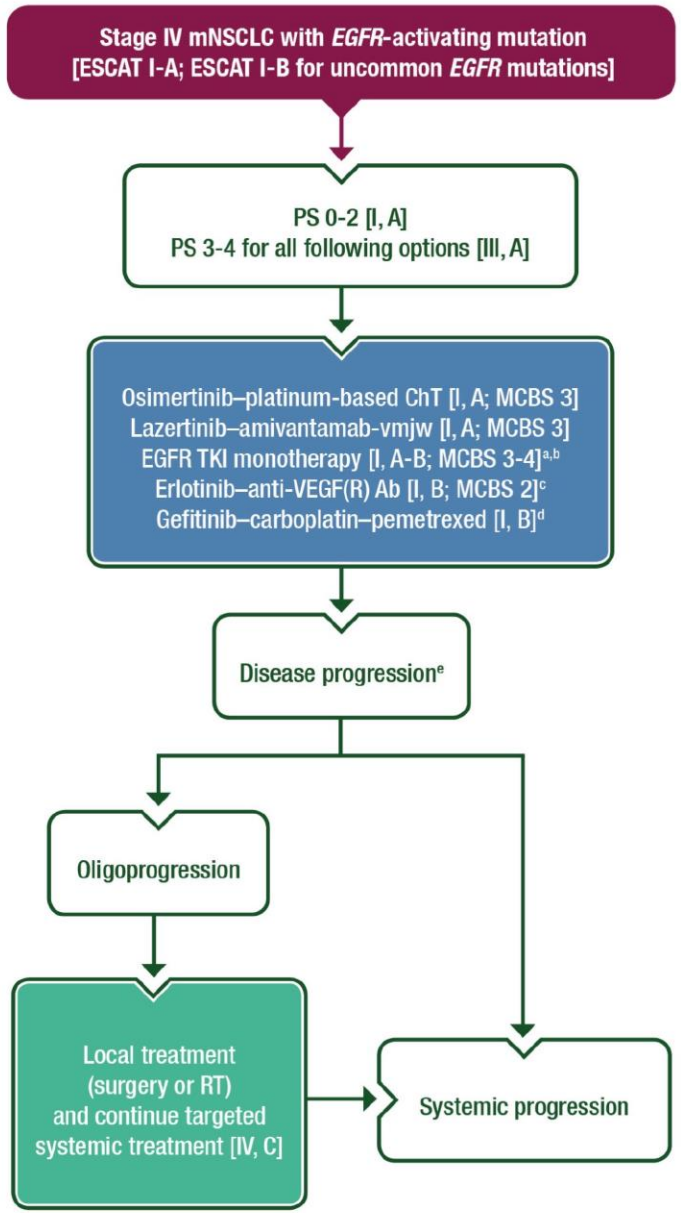
Stage IV mNSCLC with *EGFR*-activating Mutation

Before Systemic Progression

[a]Afatinib [I, B; **ESMO-MCBS v1.1 score: 4**] or osimertinib [III, B] is recommended for patients with a major uncommon, non-exon 20 insertion, sensitising *EGFR* mutation.
[b]All patients with a sensitising *EGFR* mutation should receive first-line EGFR TKIs irrespective of clinical parameters including PS, gender, tobacco exposure and histology [I, A].
[c]ESMO-MCBS v1.1 score for erlotinib–bevacizumab (EMA approved, not FDA approved) and gefitinib–bevacizumab.
[d]FDA approved, not EMA approved.
[e]Patients who have radiological progression with ongoing clinical benefit may continue with EGFR TKIs [III, A].



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First-line EGFR TKIs

EGFR exon 19 Deletion or exon 21 L858R [ESCAT: I-A]

Summary of recommendations	LoE, GoR
All patients with a sensitising *EGFR* mutation should receive first-line EGFR TKIs irrespective of clinical parameters including PS, gender, tobacco exposure and histology	I, A
Considering toxicity, cost increases with adding additional treatments and patient inconvenience, single-agent EGFR TKIs are still a standard first-line treatment	I, A
A third-generation EGFR TKI regimen is preferred for patients with a classical activating *EGFR* mutation (ex19del or ex21 L858R), either as monotherapy or combination therapy (osimertinib [**ESMO-MCBS v1.1 score: 4**]; osimertinib–pemetrexed–platinum [**ESMO-MCBS v1.1 score: 3**]; lazertinib–amivantamab-vmjw [**ESMO-MCBS v1.1 score: 3**] • PFS data seem to show a benefit in patients with baseline central nervous system metastases treated with osimertinib–chemotherapy versus those treated with osimertinib	I, A
Afatinib [**ESMO-MCBS v1.1 score: 5**], erlotinib [**ESMO-MCBS v1.1 score: 4**], gefitinib [**ESMO-MCBS v1.1 score: 4**] and dacomitinib **[ESMO-MCBS v1.1 score: 3**] are other first-line single-agent treatment options	I, B
EGFR TKIs combined with anti-angiogenic therapy are additional first-line treatment options, including erlotinib–ramucirumab [**ESMO-MCBS v1.1 score: 3**] or erlotinib–bevacizumab [**ESMO-MCBS v1.1 score: 2**; EMA approved, not FDA approved]	I, B
Another first-line option is gefitinib–carboplatin–pemetrexed [FDA approved, not EMA approved]	I, B

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First-line EGFR TKIs (2/2)

Uncommon sensitising *EGFR* mutations

Summary of recommendations	LoE, GoR
10%-20% of patients present with an uncommon, non-exon 20 insertion mutation. Afatinib [**ESMO-MCBS v1.1 score: 4**] or osimertinib are recommended for patients with a major uncommon, non-exon 20 insertion, sensitising *EGFR* mutation	I, B III, B

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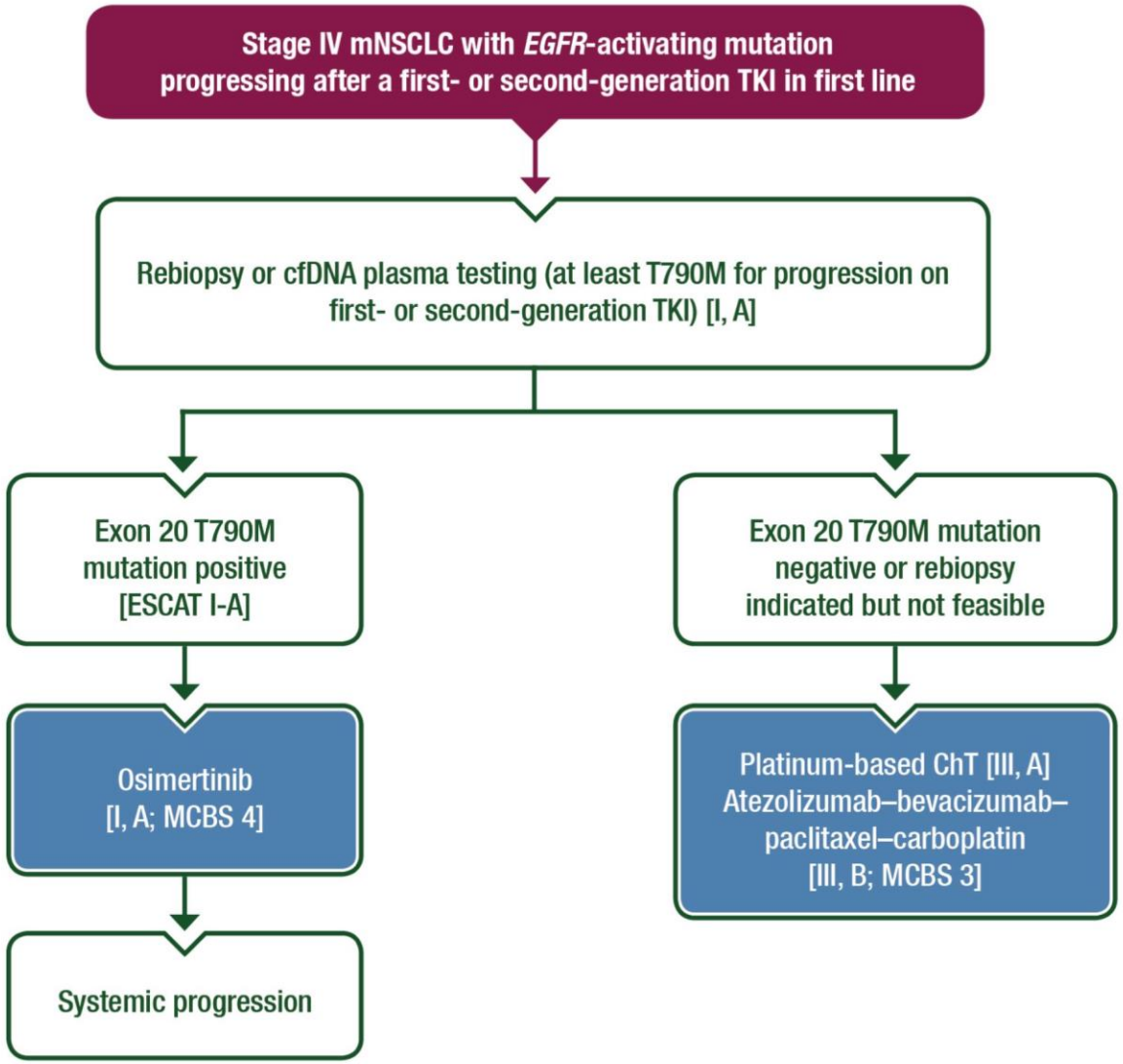
Stage IV mNSCLC with *EGFR*-activating Mutation

After Systemic Progression with First- or Second-generation TKI in First Line



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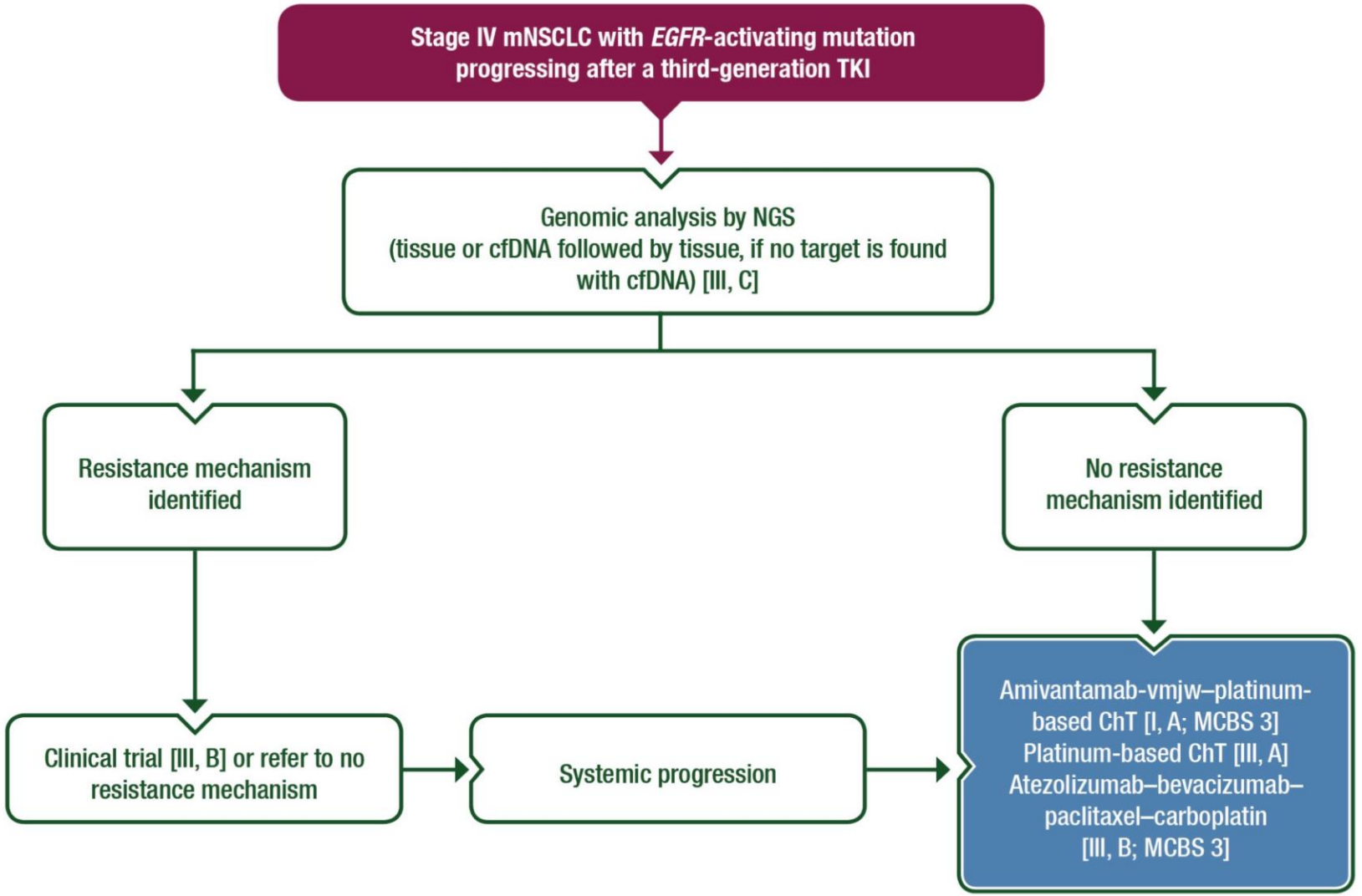
Stage IV mNSCLC with *EGFR*-activating Mutation

After Systemic Progression with a Third-generation TKI



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EGFR-mutated mNSCLC: Systemic Progression or TKI Resistance (1/2)

Summary of recommendations	LoE, GoR
Patients who have moderate radiological progression with ongoing clinical benefit may continue with EGFR TKIs	III, A
Upon resistance to first-line first- or second-generation EGFR TKIs, patients should be tested for the presence of the *EGFR* exon 20 T790M mutation from plasma cfDNA and/or tumour rebiopsy	I, A
Patients with T790M-positive resistance should receive osimertinib [**ESMO-MCBS v1.1 score: 4**] as second-line therapy T790M-negative resistance should be treated with platinum-based chemotherapy	I, A III, A
Genomic analysis by NGS (tissue or cfDNA followed by tissue, if no target is found with cfDNA) should be made available to a patient who develops resistance to EGFR TKIs	III, C

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EGFR-mutated mNSCLC: Systemic Progression or TKI Resistance (2/2)

Summary of recommendations	LoE, GoR
Upon progression on monotherapy osimertinib, recommended treatments are: • Platinum-based doublet chemotherapy • Platinum-based doublet chemotherapy with amivantamab (amivantamab-vmjw–carboplatin–pemetrexed [**ESMO-MCBS v1.1 score 3**]) The additional toxicity associated with amivantamab should be taken into account	III, A I, B
In general, clinical trial enrolment is encouraged, especially if a targetable resistance mechanism is identified	III, B
The combination of atezolizumab–bevacizumab–paclitaxel–carboplatin [**ESMO-MCBS v1.1 score: 3**] may be considered as a treatment option for patients with EGFR TKI failure, PS 0-1 and no contraindication for immune checkpoint inhibitors	III, B
Single-agent immune checkpoint inhibitors may be considered as a treatment option only after progression on EGFR TKIs and chemotherapy	IV, C

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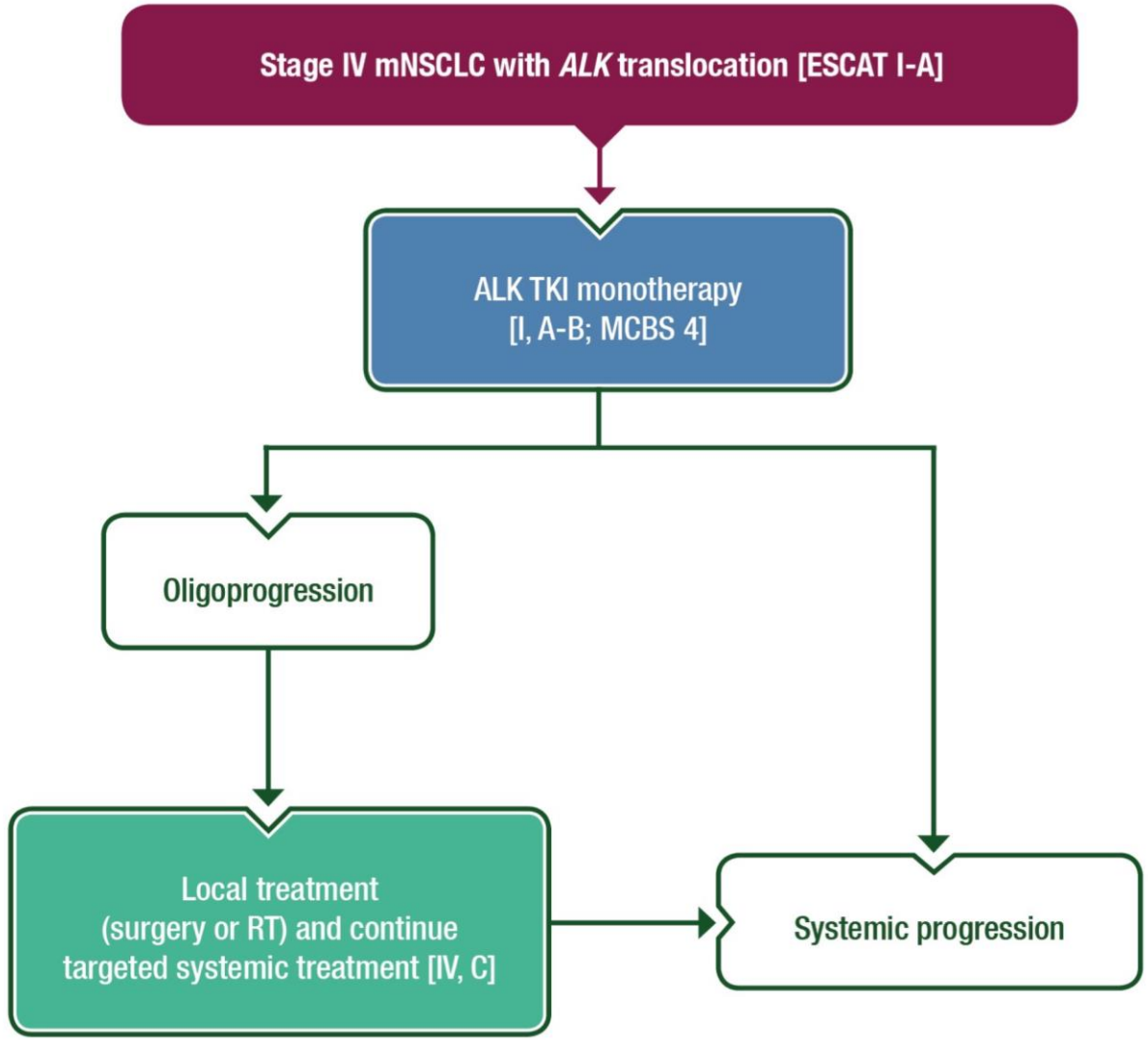
Stage IV mNSCLC with *ALK* Translocation

Before Systemic Progression



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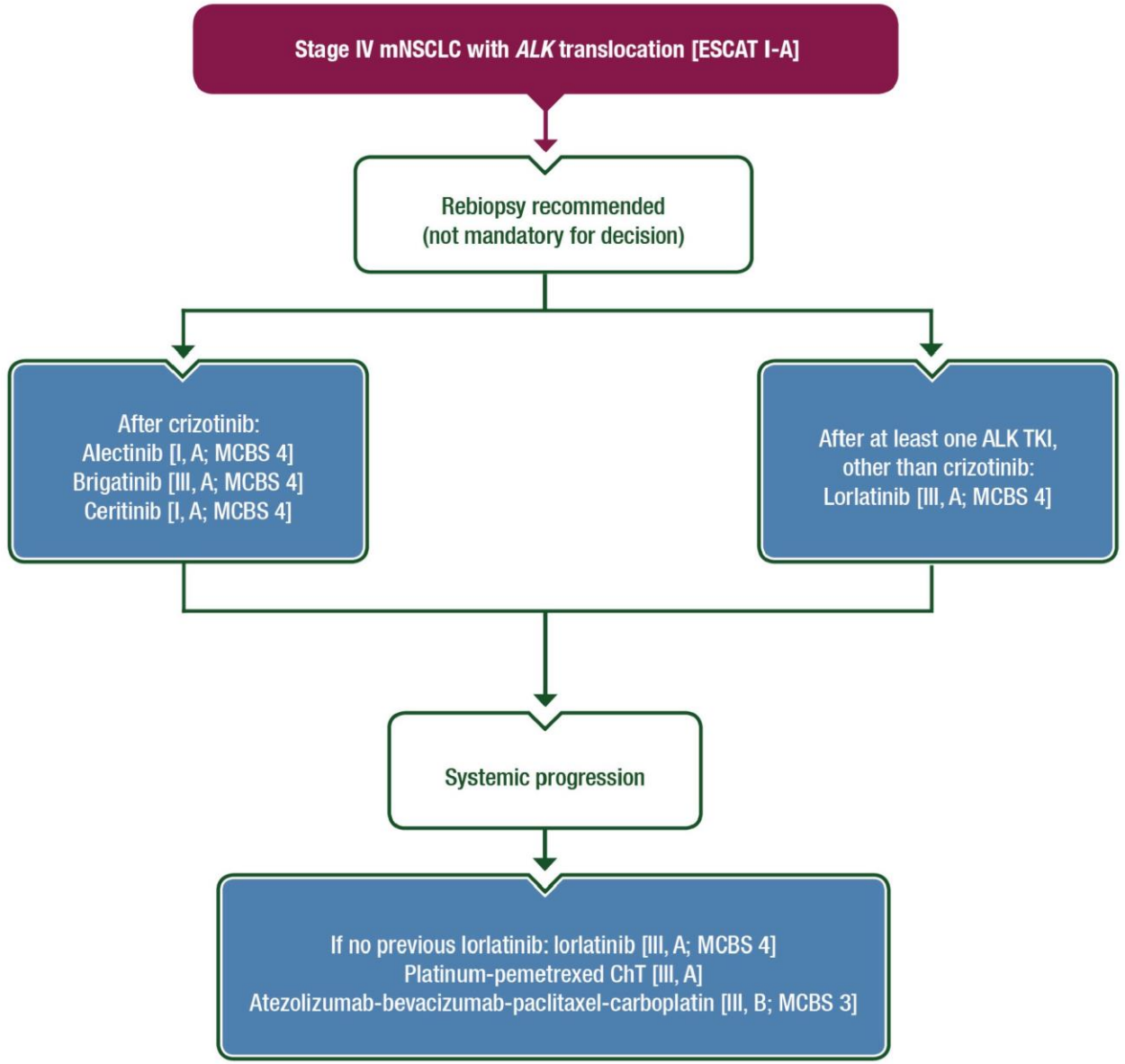
Stage IV mNSCLC with *ALK* Translocation

After Systemic Progression



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Treatment of *ALK*-positive mNSCLC

Summary of recommendations	LoE, GoR
ALK translocation [ESCAT I-A]: first-line treatment	
Patients should be treated in the first-line setting with alectinib, brigatinib or lorlatinib [for all: **ESMO-MCBS v1.1 score: 4**] These options are preferred over crizotinib or ceritinib [for all: **ESMO-MCBS v1.1 score: 4**]	I, A I, B
After progression	
Alectinib [**ESMO-MCBS v1.1 score: 4**] is recommended in patients who progress on treatment with, or are intolerant to, crizotinib	I, A
Brigatinib and ceritinib represent additional treatment options at crizotinib resistance: • Ceritinib: **ESMO-MCBS v1.1 score: 4** • Brigatinib: **ESMO-MCBS v1.1 score: 4**	I, A III, A
In patients who progress after a second-generation ALK TKI, the newer-generation ALK inhibitor lorlatinib is an option [**ESMO-MCBS v1.1 score: 4**]	III, A
Following progression on lorlatinib, chemotherapy with a platinum–pemetrexed-based combination is recommended	III, A
Following progression on lorlatinib, atezolizumab–bevacizumab–paclitaxel–carboplatin [**ESMO-MCBS v1.1 score: 3**] can be considered	III, B

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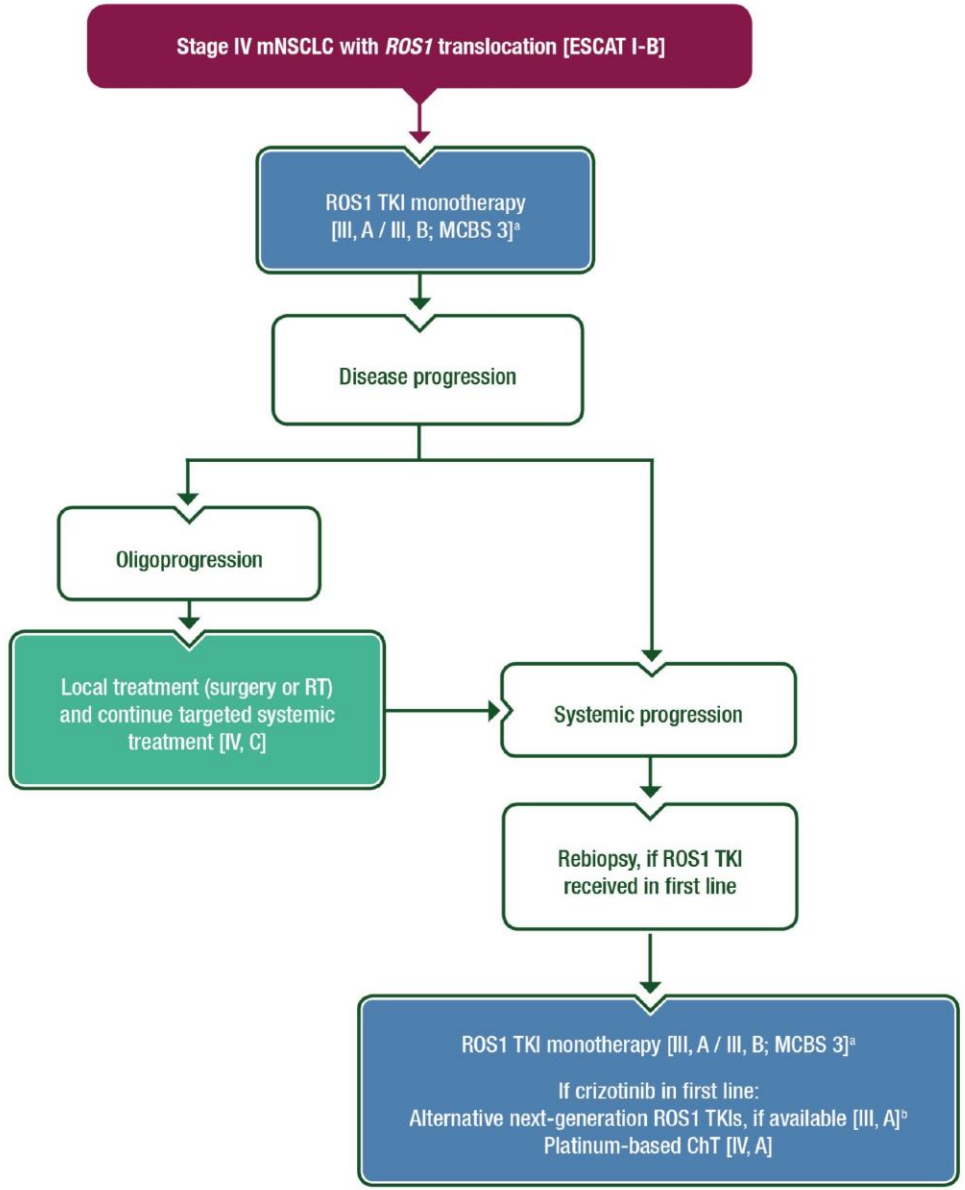
Stage IV mNSCLC with *ROS1* Translocation

[a]Entrectinib preferred over crizotinib in patients with brain metastases.
[b]FDA approved, not EMA approved.



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Treatment of *ROS1*-positive mNSCLC

ROS1 translocation [ESCAT: I-B]

Summary of recommendations	LoE, GoR
Crizotinib or entrectinib is recommended in the first-line setting [**ESMO-MCBS v1.1 score: 3**]	III, A
Entrectinib [**ESMO-MCBS v1.1 score: 3**], if available, is preferred over crizotinib in patients with brain metastases	III, A
Repotrectinib [**ESMO-MCBS v1.1 score: 3**] is also an option	III, A
If patients have received crizotinib in the first-line setting, in the second-line setting they may be offered: • Repotrectinib [**ESMO-MCBS v1.1 score: 3**] • Platinum-based chemotherapy	 III, A IV, A

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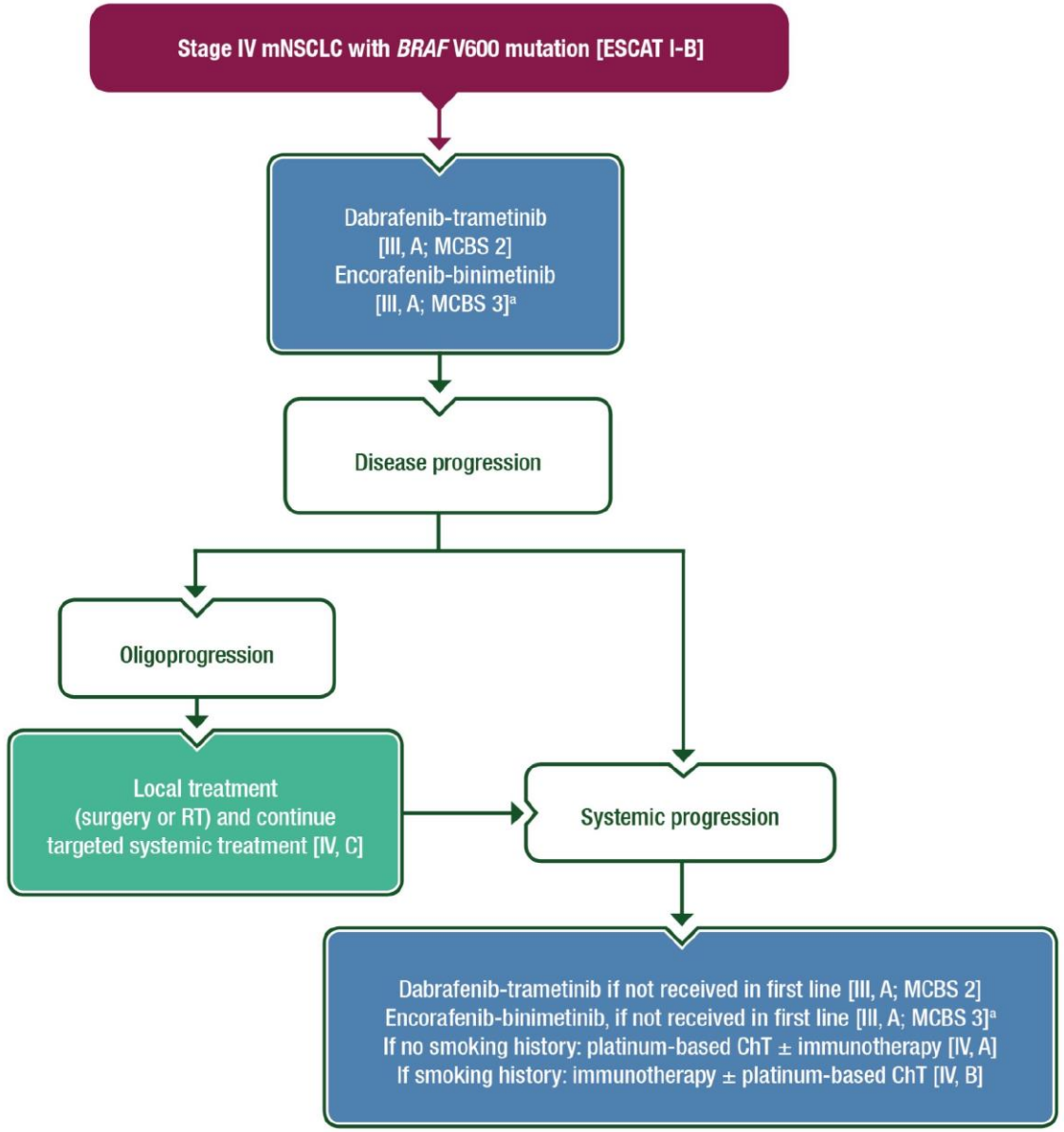
Stage IV mNSCLC with *BRAF* V600 Mutation

[a]FDA approved, not EMA approved.



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Treatment of *BRAF* mutations

BRAF mutations [ESCAT: I-B]

Summary of recommendations	LoE, GoR
BRAF-MEK inhibition is recommended using dabrafenib–trametinib [**ESMO-MCBS v1.1 score: 2**] or encorafenib–binimetinib [**ESMO-MCBS v1.1 score: 3**]	III, A
After progression, BRAF-MEK inhibition is recommended if not received in first line (encorafenib–binimetinib [**ESMO-MCBS v1.1 score: 3**]; dabrafenib–trametinib [**ESMO-MCBS v1.1 score: 2**])	III, A
If patients have received BRAF-MEK inhibition in the first-line setting, they may be offered platinum-based chemotherapy with or without immunotherapy in the second-line setting, if they do not have a smoking history For patients with a smoking history, immunotherapy with or without chemotherapy should be considered as per the ESMO CPG on Non-Oncogene-Addicted mNSCLC (Hendriks, 2023)	IV, A IV, B

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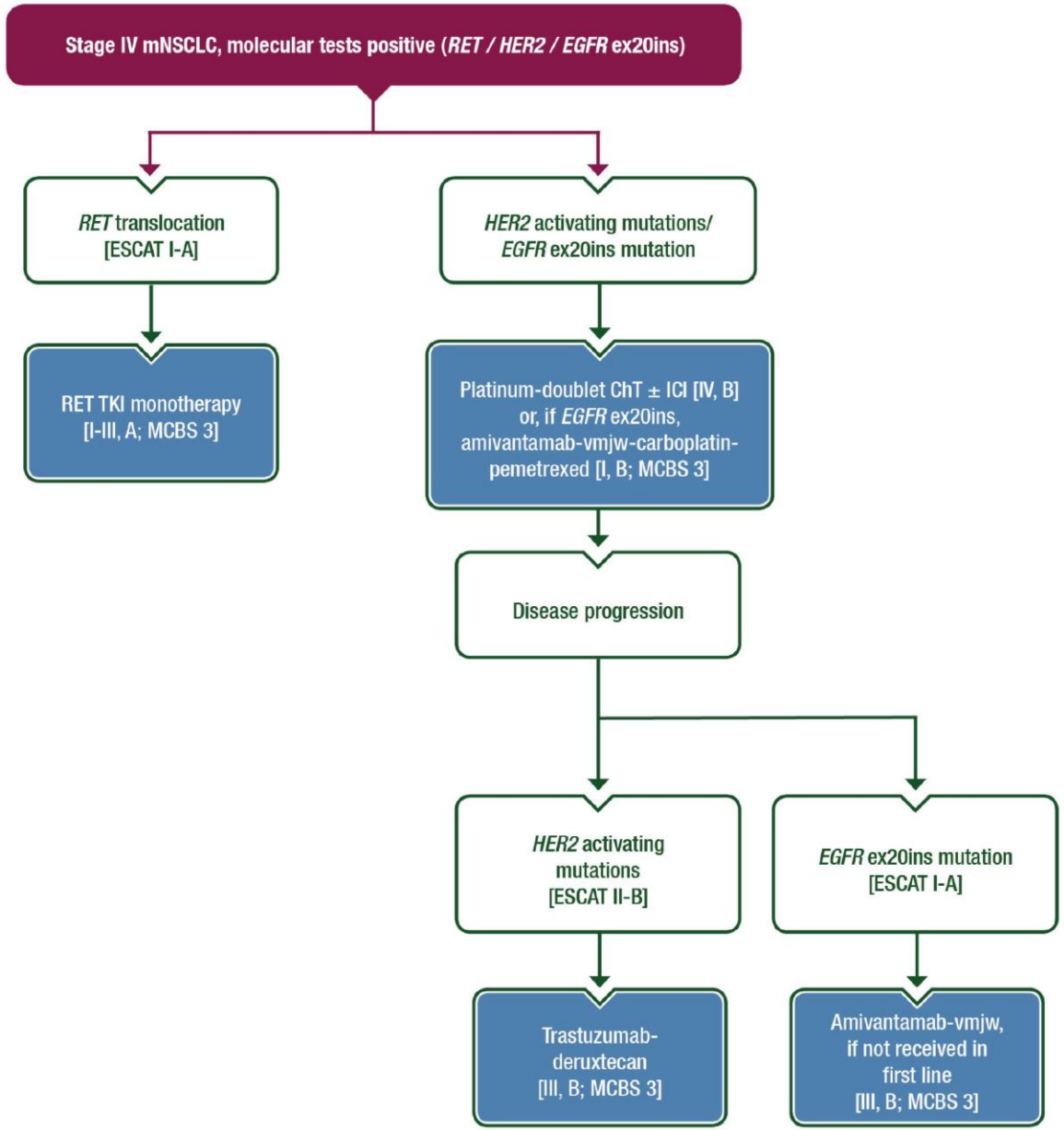
Stage IV mNSCLC, Molecular Tests Positive

RET / *HER2* / *EGFR* ex20ins



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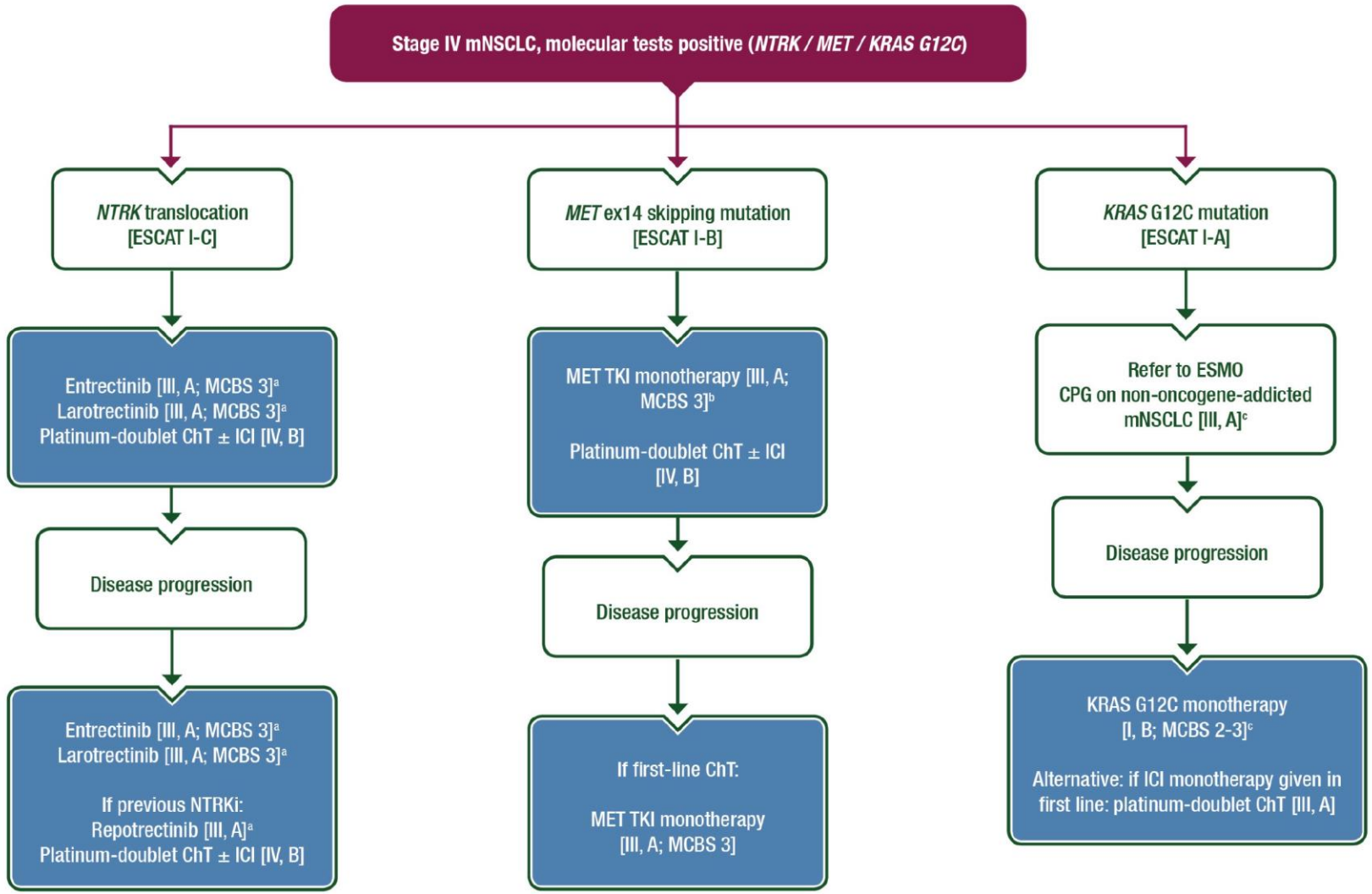
Stage IV mNSCLC, Molecular Tests Positive

NTRK / MET / KRAS G12C

[a]For patients who have no satisfactory alternative treatments
[b]Capmatinib: FDA approved, not EMA approved in first line.
[c]A parallel ESMO CPG on Non-Oncogene-Addicted mNSCLC is available at: https://www.esmo.org/guidelines/guidelines-by-topic/lung-and-chest-tumours



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Treatment of *RET* / *NTRK*

Summary of recommendations	LoE, GoR
RET translocation [ESCAT: I-A]	
Treatment with selpercatinib or pralsetinib is recommended as first-line therapy: • Selpercatinib: **ESMO-MCBS v1.1 score: 3** • Pralsetinib: **ESMO-MCBS v1.1 score: 3**	 I, A III, A
NTRK translocation [ESCAT: I-C]	
If no first-line NTRK TKI available, platinum-doublet chemotherapy with or without immune checkpoint inhibitors is recommended as first-line therapy	IV, B
Larotrectinib and entrectinib are recommended for patients who have no satisfactory treatment options, if not received before [**ESMO-MCBS v1.1 score: 3**]	III, A
Repotrectinib is recommended after progression following treatment with an NTRK inhibitor or for patients who have no satisfactory treatment options	III, A

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Treatment of *HER2* / *EGFR* ex20ins

Summary of recommendations	LoE, GoR
***HER2* activating mutation [ESCAT: II-B]**	
Platinum-doublet chemotherapy with or without immune checkpoint inhibitors is recommended as first-line therapy	IV, B
Trastuzumab deruxtecan is recommended following prior first-line therapy [**ESMO-MCBS v1.1 score: 3**]	III, B
***EGFR* exon 20 insertion-mutation [ESCAT: I-A]**	
Amivantamab–carboplatin–pemetrexed is recommended as first-line therapy [**ESMO-MCBS v1.1 score: 3**]	I, B
If not available, platinum-doublet chemotherapy with or without immune checkpoint inhibitors is recommended as first-line therapy	IV, B
Amivantamab is recommended for treatment of patients failing prior therapy which did not contain amivantamab [**ESMO-MCBS v1.1 score: 3**]	III, B

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Treatment of *MET* / *KRAS* G12C

Summary of recommendations	LoE, GoR
MET exon 14 skipping mutation [ESCAT: I-B]	
Capmatinib (FDA approved, not EMA approved) and tepotinib in first line or in second line are recommended: • Capmatinib (first line) [**ESMO-MCBS v1.1 score: 3**, FDA approved, not EMA approved] • Capmatinib (following prior platinum-doublet chemotherapy with or without immune checkpoint inhibitors) [**ESMO-MCBS v1.1 score: 3**] • Tepotinib (first line or following prior platinum-doublet chemotherapy with or without immune checkpoint inhibitors) [**ESMO-MCBS v1.1 score: 3**]	III, A
If no MET TKI is available in the first line, platinum-doublet chemotherapy with or without immune checkpoint inhibitors is recommended as first-line therapy	IV, B
KRAS G12C-mutation [ESCAT: I-A]	
It is recommended to follow the first-line treatment algorithms in the ESMO CPG on Non-Oncogene-Addicted mNSCLC (Hendriks, 2023)	III, A
Sotorasib [**ESMO-MCBS v1.1 score: 3**] or adagrasib [**ESMO-MCBS v1.1 score: 2**] are recommended for treatment of patients failing prior therapy	I, B
Platinum-doublet chemotherapy can be given after progression on first-line monotherapy ICI	III, A

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Special Populations

Summary of recommendations	LoE, GoR
TKIs should be given to patients with PS ≥2 and an oncogenic driver	III, A
TKIs should be given to elderly patients	II, A
Patients with oligometastatic disease at diagnosis may experience long-term PFS following systemic therapy and local ablative therapy (high-dose radiotherapy or surgery), but due to limited evidence, inclusion in clinical trials is preferred	II, B
Patients with advanced NSCLC and a driver mutation, with oligoprogression while on molecular-targeted therapy, may benefit from local ablative therapy (high-dose radiotherapy or surgery) including improved long-term DFS, but data are limited and inclusion in clinical trials is preferred	-

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Follow-up, Palliative Care and Survivorship

Summary of recommendations	LoE, GoR
Follow-up, long-term implications and survivorship	
Follow-up every 8-12 weeks should be carried out if there is an option for a next line of therapy	IV, A
Psychosocial support should be offered if needed	IV, A
Smoking cessation should be encouraged	IV, A
Palliative care in stage IV	
Early palliative care intervention is recommended, in parallel with standard oncological care	I, A

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Glossary

AJCC, American Joint Committee on Cancer
ALK, anaplastic lymphoma kinase
ChT, chemotherapy
cfDNA, circulating free DNA
CPG, Clinical Practice Guideline
CT, computed tomography
DFS, disease-free survival
DNA, deoxyribonucleic acid
ECOG, Eastern Cooperative Oncology Group
EGFR, epidermal growth factor receptor
EMA, European Medicines Agency
ESCAT, ESMO Scale for Clinical Actionability of molecular Targets
ESMO, European Society for Medical Oncology
ESMO-MCBS, ESMO-Magnitude of Clinical Benefit Scale
FDA, Food and Drug Administration
FDG, [18F]2-fluoro-2-deoxy-D-glucose
FISH, fluorescence in situ hybridisation
ICI, immune checkpoint inhibitor
IHC, immunohistochemistry
KRAS, Kirsten rat sarcoma virus
MCBS, ESMO-Magnitude of Clinical Benefit Scale
MET, MET proto-oncogene tyrosine-protein kinase
mNSCLC, metastatic non-small-cell lung cancer
MRI, magnetic resonance imaging
NGS, next generation sequencing
NSCLC, non-small-cell lung cancer
PET, positron emission tomography
PFS, progression-free survival
PS, performance status
RET, proto-oncogene tyrosine-protein kinase Ret
ROS1, proto-oncogene tyrosine-protein kinase ROS
RECIST, Response Evaluation Criteria in Solid Tumours
RNA, ribonucleic acid
RT, radiotherapy
TKI, tyrosine kinase inhibitor
TNM, tumour–node–metastasis
UICC, Union for International Cancer Control
VEGFR, vascular endothelial growth factor
WHO, World Health Organization

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Disclaimer and how to obtain more information

This slide set provides you with the most important content of the full ESMO Clinical Practice Guideline (CPG) on the management of Oncogene-Addicted Metastatic Non-small-cell Lung Cancer (NSCLC). Key content includes diagnostic criteria, staging of disease, treatment plans and follow-up (*Ann Oncol*. 2023;34(4):339-357).
The slide set is based on the latest information in the corresponding ESMO Living Guideline:
https://www.esmo.org/living-guidelines/esmo-oncogene-addicted-non-small-cell-lung-cancer-living-guideline

The ESMO CPGs are intended to provide you with a set of recommendations for the best standards of care, using evidence-based medicine. Implementation of ESMO CPGs facilitates knowledge uptake and helps you to deliver an appropriate quality of focused care to your patients.

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