Personalized Medicine testing recommendations for:

NSCLC - Adenocarcinoma, Large Cell, NOS

Newly Diagnosed, Non-Metastatic (somatic)

When and what should be tested?

- Treatment eligible
- Stage IB-IIIA
- Stage IIIA with local recurrence
- Newly diagnosed or local recurrence
- Tissue sample preferred
- Liquid biopsy if tissue sample is inadequate for further testing

FDA/NCCN approved*

- Stage IB-IIIA
  - EGFR (exon 19 or L858R)
  - PD-L1
  - ALK rearrangement

Emerging

- Comprehensive NGS panel preferred, payer permitting
  - Sequential single gene testing not preferred due to likelihood of running out of tissue
- MRD

*Prior to finalizing plans for treatment, it is essential to follow approved testing recommendations and await test results

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Personalized Medicine testing recommendations for:

NSCLC - Adenocarcinoma, Large Cell, NOS

Advanced/Metastatic Disease at Initial Diagnosis (somatic)

When and what should be tested?

- Treatment eligible
- Stage IIIB/C or Stage IV
- Test at initial work-up
- Tissue sample preferred for initial testing
- Peripheral blood when insufficient tissue
- Testing should be conducted as part of multigene panel testing (MGPT)

FDA/NCCN approved*

- EGFR
- ALK
- ROS1
- BRAF/ BRAF V600E
- KRAS / KRAS G12C
- NTRK 1/2/3**
- MET Exon 14 skipping
- RET
- TMB
- dMMR/MSI
- NRG1
- ERBB2

Test by IHC

- HGF receptor (c-MET)
- PD-L1
- HER-2/ERBB2

Emerging

- High-level MET amplification
- FGFR alterations
- PIK3CA

*Prior to finalizing plans for treatment, it is essential to follow approved testing recommendations and await test results

**If no driver alteration identified on DNA NGS, assure testing by RNA NGS.

*** Maximal identification of driver mutations has been observed when both liquid and tissue comprehensive profiling is completed.

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Personalized Medicine testing recommendations for:

NSCLC - Adenocarcinoma, Large Cell, NOS

Advanced/Metastatic Disease at Time of Disease Progression (somatic)

When and what should be tested?

- Treatment eligible
- Stage IIIB/C or IV
- Test at initial work-up
- Studies have shown maximum driver identification when both tissue and peripheral blood is evaluated

FDA/NCCN approved

- If not completed initially, complete comprehensive NGS panel via tissue biopsy and/or liquid biopsy*
- To identify all potential treatment options, including clinical trials, consider comprehensive genomic testing again, if appropriate.

Emerging

- EGFR C797S
- Cell cycle gene amplifications
- PIK3CA

*All NGS panels should include FDA-approved and clinically supported biomarkers including, but not limited to, EGFR (T790, exon 19-21), ALK, ROS1, PD-L1, TMB, dMMR, BRAF, KRAS G12C, RET, MET, NTRK, and HER2 mutation. When sufficient tissue is available (or even liquid biopsy is an option), comprehensive genomic profiling is appropriate to identify driver mutations

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Personalized Medicine testing recommendations for:

NSCLC - Squamous

Newly Diagnosed, Non-Metastatic (somatic)

When and what should be tested?

- Treatment eligible
- Stage IB-IIIA
- Newly diagnosed or upon local recurrence
- Tissue sample preferred
- Liquid biopsy if tissue sample is inadequate for further testing

FDA/NCCN approved*

- Stage IB- IIIA
  - EGFR (exon 19 or L858R)
  - PD-L1
  - ALK rearrangement

Emerging

- Comprehensive NGS panel preferred, payer permitting
  - Sequential single gene testing not preferred due to likelihood of running out of tissue
- MRD

*When sufficient tissue is available (or even liquid biopsy is an option), comprehensive genomic profiling is appropriate to identify driver mutations

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Personalized Medicine testing recommendations for:

NSCLC - Squamous

Advanced/Metastatic Disease (somatic)

When and what should be tested?

- Treatment eligible
- Stage IIIB/C non-curative intent or Stage IV
- Newly diagnosed or upon progression to at least stage IIIB
- Studies have shown maximum driver identification when both tissue and peripheral blood is evaluated

FDA/NCCN approved*

- EGFR
- ALK
- KRAS
- ROS1
- BRAF / BRAF V600E
- NTRK 1/2/3
- MET exon 14
- RET
- dMMR/MSI
- TMB
- NRG1
- ERBB2

Test by IHC

- PD-L1
- c-MET/MET/HGFR
- HER-2/ERBB2

Emerging

- PIK3CA
- High level MET amplification
- FGFR alterations

*When sufficient tissue is available (or even liquid biopsy is an option), comprehensive genomic profiling is appropriate to identify driver mutations

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