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An initiative to drive the best treatment decisions with complete biomarker testing

Backgrounder: Biomarker Testing in Non-Small Cell Lung Cancer

First-line treatment of advanced non-small cell lung cancer (NSCLC) lags behind recommended medical guidelines

Many patients receive inappropriate therapy due to guideline non-adherence

- Medical guidelines have expanded over the past 10 years and now recommend all patients with metastatic or advanced non-small cell lung cancer undergo biomarker testing for EGFR, ALK, ROS1, BRAF, NTRK, MET, RET, ERBB2, and KRAS[1-3]
- Adoption of precision oncology (treatment based on an individual's cancer genetic data) for advanced NSCLC lags behind recommended standard-of-care medical guidelines[4]
- Fewer than 20% of people with advanced NSCLC receive complete guideline-recommended biomarker testing. This puts many advanced NSCLC patients at risk for inappropriate treatment[4]
- Approximately 21% of advanced NSCLC patients have biomarkers associated with drugs currently approved by the FDA[5]
- Various factors contribute to clinical adoption of precision oncology lagging behind recommended medical guidelines, including: physician-reported gaps in the knowledge and skills needed to incorporate genotyping into clinical practice; challenges in keeping track of the latest recommendations; the timeframe associated with getting complete genotyping results; and the cost of tests when not covered by insurance[4,6-8]

Personalized treatment decisions shown to improve outcomes

The presence of specific mutations plays a role in the response to corresponding targeted drugs.[9-15]

Genetic mutation	Associated therapy (response rate)
EGFR exon 19 del, L858R and other alterations	TAGRISSO®, TARCEVA®, GILOTRIF®, IRESSA®, VIZIMPRO® (60-80%)[16-24]
ALK fusions	ALECENSA®, ALUNBRIG®, ZYKADIA®, XALKORI®, LORBRENA® (40-80%)[25-31]
ROS1 fusions	XALKORI®, ROZLYTREK™ (72-78%)[28,32]
BRAF V600E	TAFINLAR® + MEKINIST® (65%)[31]
NTRK fusions	VITRAKVI®, ROZLYTREK™ (57-75%)*[32,33]
MET exon 14 skipping and amplifications	XALKORI®^ (40-50%)[34-35]
RET fusions	CABOMETYX®^, CAPRELSA®^(20-50%)[36-38]
ERBB2 exon 20 insertions and other alterations	KADCYLA®^ (45%), HERCEPTIN®^ combinations (50%)[39-40]
KRAS mutations	*KRAS mutations usually do not overlap with other driver mutations and can indicate that no additional genomic testing is necessary*[41-43]

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^US FDA-approved in another indication
+For patients who meet specific coverage criteria
*Response rate is based on studies involving multiple cancer types

Only one chance

Many physicians rush to recommend immunotherapy as a patients' initial treatment, but it's not always the right option. Some patients with certain mutations can do worse when treated with immunotherapy. For example, patients with EGFR, ALK, or BRAF alterations have a lower overall response rate to immunotherapy than they do to targeted therapy. [44-50]

There is only one opportunity for the right initial treatment decision. Only one in two patients make it to second-line therapy.[51]

The right therapy **matched to the patient's genomic profile** can significantly extend survival compared to chemotherapy alone. [52-58]

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