Key takeaways

- Biomarker testing (also known as mutation, genomic, or molecular testing) uses laboratory tests to help the health care team gather as much information as possible about a patient’s disease state.

- Biomarker testing is critical, because it can help providers make more informed treatment decisions, reduce total cost of care, and align with health system level strategic priorities.

- Biomarker testing is disrupting two elements of healthcare: care delivery, and cost/payment models.
DISRUPTIVE THERAPEUTICS AND DIAGNOSTICS SERIES

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Biomarker Testing

Biomarker testing (also known as mutation, genomic, or molecular testing) uses laboratory tests to help the health care team gather as much information as possible about a patient’s disease state.

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What is biomarker testing?

A biomarker is a characteristic that can be scientifically measured or evaluated as an indicator of normal biologic processes, disease, or response to therapeutic intervention. The major types of biomarkers include molecular, histologic, radiographic, and physiologic characteristics. Examples of biomarkers include blood pressure, blood glucose levels, imaging results, cancer grades and stages, protein expression (e.g., PD-L1), genetic indicators (e.g., genetic driver mutations like EGFR). As the field of precision medicine grows, the focus on genetic biomarkers has grown as well. The following sections will focus on biomarker testing in oncology.

Biomarker testing (also known as mutation, genomic, or molecular testing) uses laboratory tests to help the health care team gather as much information as possible about a patient's disease state. There are four categories of biomarker testing: predisposition, diagnostic, prognostic, and predictive.

- **Predisposition:** A certain genetic biomarker could indicate an increased risk or susceptibility to a given disease
- **Diagnostic:** Distinguish between health and disease
- **Prognostic:** Predict natural history of disease in absence of further intervention (e.g., testing for chemotherapy response, testing hereditary markers for risk)
- **Predictive:** Predict an outcome following an intervention (e.g., response or lack of response to drug); usually a companion diagnostic (CDx)

A comparison diagnostic (CDx) is typically an in vitro diagnostic that detects a predictive biomarker to determine the likely efficacy of a corresponding drug or biological product. For example, FoundationOne® CDx is an FDA-approved, tissue-based broad CDx that physicians can use to analyze the patient's individual genomic profile and inform treatment decisions for over 20 FDA-approved targeted therapies. Clinicians should order the corresponding CDx to determine appropriate therapeutic options for each patient.

Why does it matter?

Biomarker testing can help providers make more informed treatment decisions based on a patient’s genomic makeup or the genomic makeup of their condition. On a population health level, biomarkers can give us a glimpse into our future health status, with the possibility of one day being able to look at a molecular profile and identifying mutations that may predispose patients to certain diseases.

Biomarker testing is also important in improving the efficacy and success of drug development. Biomarkers can tell a story about toxicity and safety. Biomarkers are integral to drug development and for the advancement of clinical trials.

Additionally, biomarker testing can align with a health system’s broader strategic goals. For example, with the shift to value-based care, many organizations are focused on delivering appropriate, high-value care. Many organizations are focused on expanding their precision medicine programs to provide patients with more informed, personalized care. Biomarker testing aligns with each of these health system strategic priorities.

The market is poised to grow significantly over the next decade, with increased R&D effort and investment. A recent report stated that the global market for cancer biomarker testing is expected to exceed US$ 34 Billion by 2032, representing a threefold increase from 2022. The market is currently worth slightly more than US$ 11 Billion.

$34B

The global market for cancer biomarker testing is expected to exceed $34 billion by 2023, which would be a threefold increase from 2022.

What makes it disruptive?

Areas of disruption

Care delivery

Biomarker testing has disrupted the way physicians think about testing because it incorporates all biomarkers (genomic and non-genomic) testing that patients with complex disease states such as cancer need and can be useful at multiple points throughout a patient’s care journey. Biomarker testing may disrupt diagnosis by allowing for more specific diagnoses, and as a result, this will have implications on treatment matching, and treatment monitoring and response.

Cost/payment models

Payment models for biomarker testing and reimbursement is an evolving landscape, but coverage tends to be better under Medicare and large employer-sponsored plans.

Additionally, reimbursement for biomarker testing is not consistent across therapeutic areas and different commercial health plans. As a result, coverage and cost concerns is a barrier to adoption for many health systems and poses a barrier for patients who may benefit from precision medicine the most. Today, health plans are hesitant to cover precision medicine because there is not proof of efficacy at the population level. This reticence is common for rare diseases, where treatments put financial strain on the system for a small subset of the population.

With the advent of new payment models, pharmacogenomics could get patients to the right treatment that is tailored to their specific needs, which could reduce the long-term overall costs associated with the traditional trial-and-error method of care. This in turn would reduce costs in medications over time and hospital readmissions.

What makes it disruptive?

A note on health equity

Whether biomarker testing alleviates or exacerbate health disparities will depend on the degree to which genetic data is representative of the broader patient population.

However, some new tests may be taken up less quickly and in lower numbers in underserved and minority populations due to barriers to access, availability, ability to pay privately, and lower health literacy.

For biomarker testing marginalized groups, as well as ongoing community partnerships to advance health equity for all populations, healthcare leaders must think intersectionally about how to address systemic issues and not perpetuate them in practice. There needs to be education and communication considerations specific to build awareness and trust.
Conversations you should be having

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<td>• What are the clinical use cases for biomarker testing in my patient population? At which points in the care cascade will biomarker testing be most helpful?</td>
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<td>• How can we educate those in our system on payer and manufacturer policies related to biomarker testing?</td>
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<td>• How can we standardize our biomarker testing process across all appropriate clinicians and sites?</td>
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<td>• How do we educate patients on biomarker testing?</td>
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<td>• How can we codify our processes and procedures to facilitate widespread adoption of those standards?</td>
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<td>• What are long-lasting, sustainable investments we can make in our biomarker testing process to support our push towards precision medicine?</td>
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