

Precision Oncology Continues to Redefine Cancer Treatment:

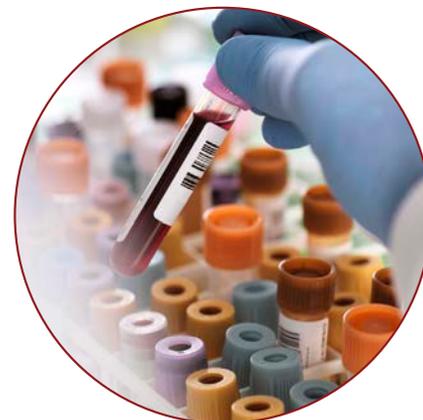
The Ongoing Revolution in Oncology Care

Results of *The Precision Oncology Annual Trend Report, Seventh Edition*, sponsored by Novartis Oncology, reveal the growing impact and importance that predictive biomarker tests have on treatment decision-making.

NGS Continues to Revolutionize Precision Oncology and Patient Care¹

How is precision oncology and NGS testing evolving in your organization?

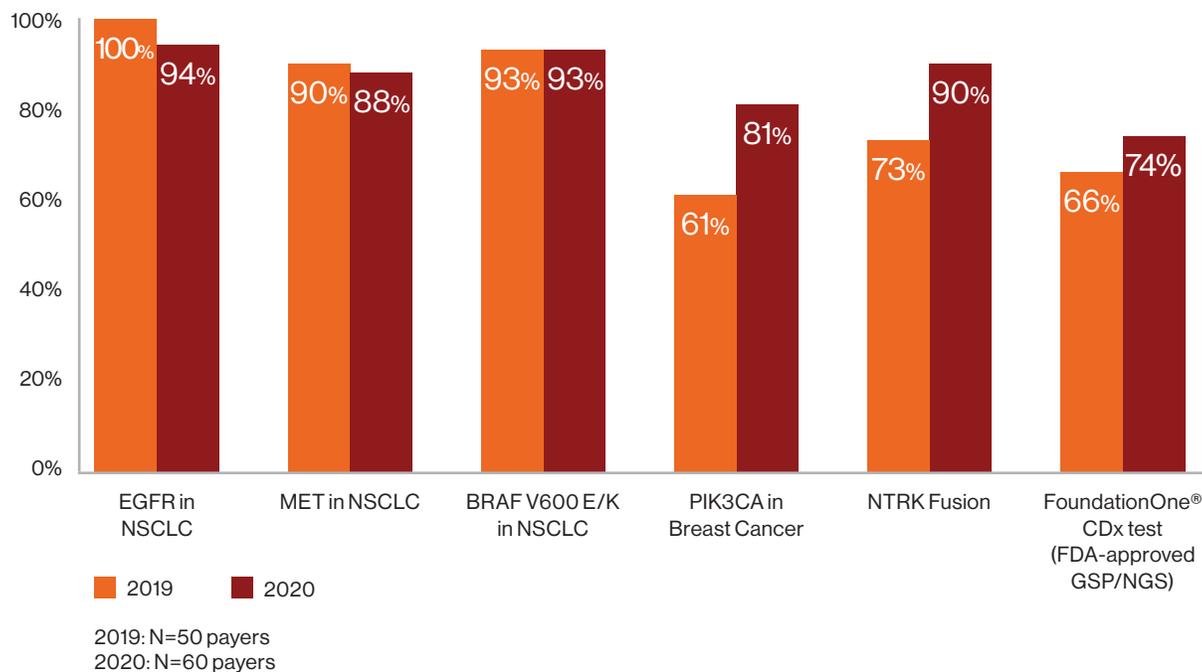
Use of NGS/GSP biomarker testing continues to revolutionize precision medicine in oncology; however, logistic challenges remain for NGS/GSP, including the time to get results and obtaining sufficient tumor biopsy tissue. This has driven some to adopt “liquid biopsies.” The increase in biomarker test data and number of approved therapeutics to address mutations has created additional interpretation and cost challenges for all stakeholders.



Increasing Coverage of Companion Diagnostics and NGS¹

How does biomarker coverage in your organization compare to this national data?

From 2019 to 2020, some changes occurred in payer coverage of the biomarker tests listed below



CDx, companion diagnostics; FDA, US Food and Drug Administration; GSP genomic sequencing panel; NGS, next-generation sequencing; NSCLC, non-small cell lung cancer.

The Potential of Biomarkers²⁻⁵

Understanding the role of biomarkers and companion diagnostics is essential to helping payers continue to improve patient care.



Cost Effectiveness—Recent Oncotype DX® Data

Data presented in October 2020 suggested that using the Oncotype DX Breast Recurrence Score® can help guide treatment decision-making for early-stage, hormone-receptor-positive, HER2-negative breast cancer regardless of lymph node involvement. The data showed that the results of the test changed treatment recommendations for 33.5% of patients and that the treatment decisions reduced chemotherapy recommendations by 23.5%.⁶

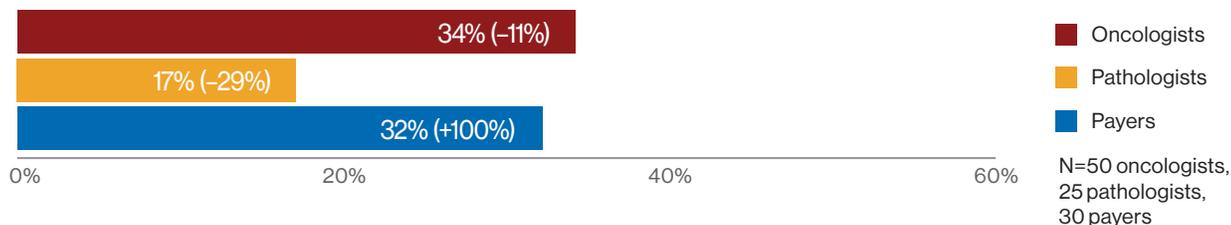
Oncotype DX–guided treatment could reduce the cost for the first year of breast cancer care in the United States by approximately \$50 million (~2% of the overall costs in the first year).⁷

Stakeholder Opinions on NGS/GSP¹

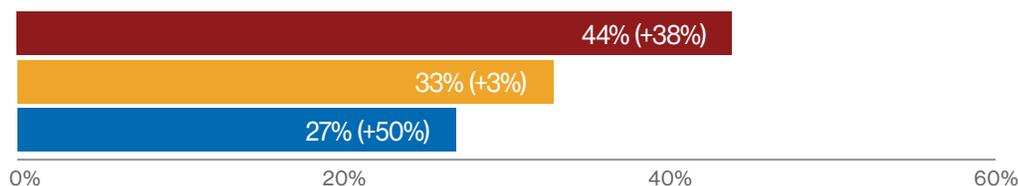
When does your organization support the use of NGS biomarker testing?

The development of NGS technology will increase the opportunity to identify multiple cancer-related gene mutations in a single, rapid, low-cost test. The chart below reflects the opinions of NGS/GSP test utilization timing.

Full NGS/GSP conducted on all tumor biopsies at diagnosis



Full NGS/GSP conducted on all tumor biopsies upon disease progression

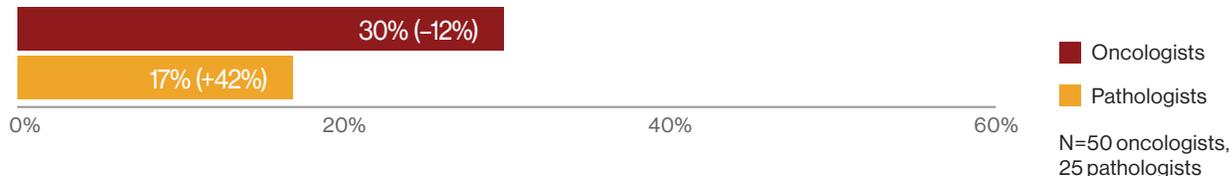


Values in parentheses indicate percent change from 2019.

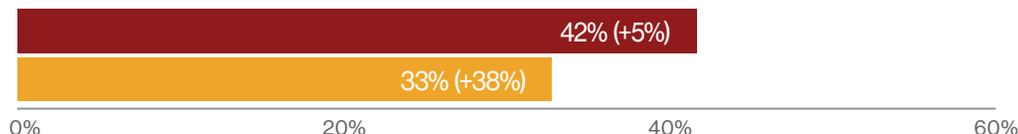
What hurdles remain for wider adoption of NGS biomarker testing in your organization?

Provider Opinions on NGS/GSP Testing Process

Obtaining enough tumor from the biopsy for the test is not a problem



The time required to acquire a biopsy and receive the test results can be an issue



Data presented reflect those who strongly agreed with the statements above. Those who were neutral or strongly disagreed are not depicted.

Values in parentheses indicate percent change from 2019.

In January 2020, CMS announced that it would **cover all biomarker testing for breast and ovarian cancer–related germline mutations.**⁸



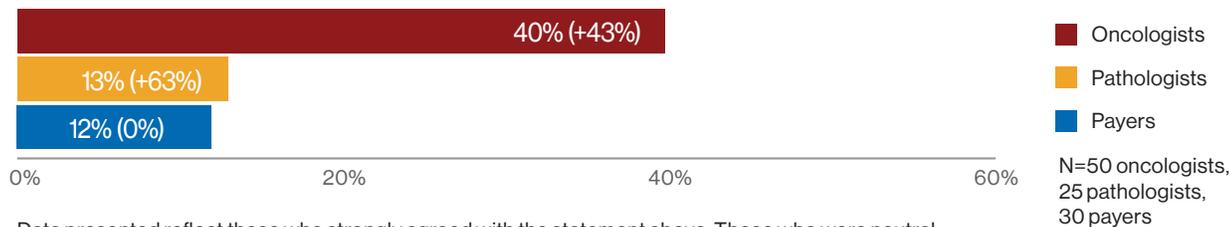
Liquid Biopsies Continue to Be Evaluated¹

How is the use of liquid biopsies evolving in your organization?

Stakeholders continue to evaluate the clinical utility of ctDNA NGS “liquid biopsy” tests—**40% of oncologists, 13% of pathologists, and 12% of payers strongly agree** that enough evidence exists to incorporate ctDNA NGS “liquid biopsy” tests into routine clinical practice.

Utilization Considerations for ctDNA NGS “Liquid Biopsy” Test

Sufficient evidence exists to incorporate ctDNA NGS/GSP “liquid biopsy” tests into routine clinical practice



Data presented reflect those who strongly agreed with the statement above. Those who were neutral or strongly disagreed are not depicted.

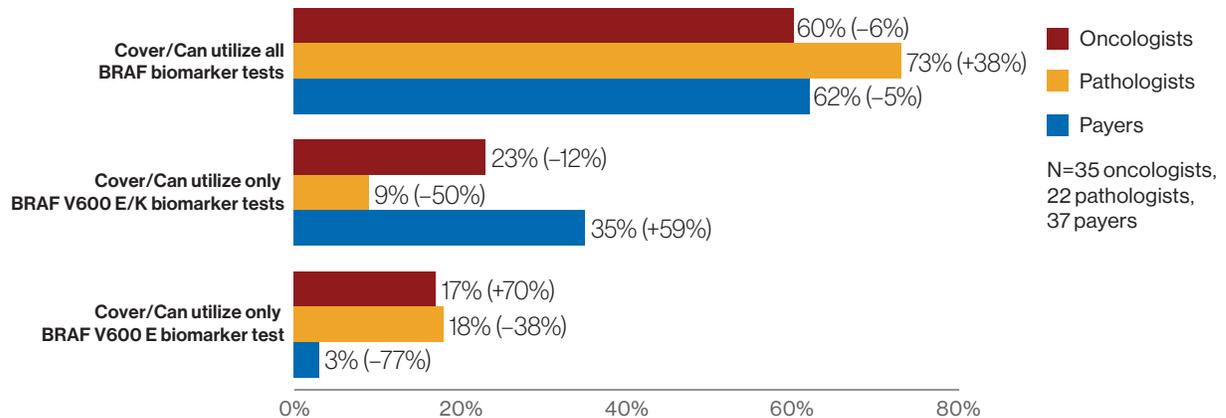
Values in parentheses indicate percent change from 2019.

Coverage Policies or Utilization Guidance for BRAF Biomarker Tests in Melanoma¹

What are the coverage or utilization policies for BRAF in your organization?

Providers (**60% of oncologists and 73% of pathologists**) reported their organization includes all **BRAF tests** in their utilization guidelines. Sixty-two percent of payers reported their coverage policies stipulate that all BRAF biomarker tests for melanoma are covered.

Organizations' BRAF Biomarker Test Pathway or Guidance Policy



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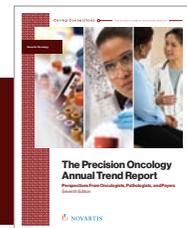
What precision oncology topics interest you?

Key Insights From *The Precision Oncology Annual Trend Report*¹

- NGS continues to revolutionize precision oncology and patient care
- Laboratory benefit managers are becoming more influential
- Clinical validity is the **most important driver** of biomarker test coverage by payers
- Many large national payers have adopted less stringent management of oncology biomarkers, including NGS panels
- Liquid biopsies are being adopted into routine clinical practice
- Following the CMS decision to cover NGS companion diagnostics, 74% of payer respondents indicated covering FoundationOne® CDx in 2020

FoundationOne is a registered trademark of Foundation Health, Inc.

For a copy of *The Precision Oncology Annual Trend Report*,
contact your Novartis representative
 or visit hcp.novartis.com/care-management.



References: 1. Novartis Oncology. *The Precision Oncology Annual Trend Report: Perspectives From Oncologists, Pathologists, and Payers*. 7th ed; 2021. 2. Schneider JE, Sidhu MK, Doucet C, Kiss N, Ohsfeldt RL, Chalfin D. Economics of cancer biomarkers. *Per Med*. 2012;9(8):829-837. 3. World Health Organization. Biomarkers in risk assessment: validity and validation. <http://www.inchem.org/documents/ehc/ehc/ehc222.htm>. Accessed May 21, 2020. 4. Goossens N, Nakagawa S, Sun X, Hoshida Y. Cancer biomarker discovery and validation. *Transl Cancer Res*. 2015;4(3):256-269. 5. American Association for Cancer Research. *AACR Cancer Progress Report 2017, Harnessing Research Discoveries to Save Lives*. Philadelphia: American Association for Cancer Research; 2017. 6. Thill M, Anastasiadou L, Solbach C, et al. The REMAR (Rhein-Main-Registry) study: prospective evaluation of Oncotype DX assay in addition to Ki-67 for adjuvant treatment decisions in early breast cancer. Presented at 12th European Breast Cancer Conference (EBCC-12); October 2, 2020. *Euro J Cancer*. 2020;138(suppl 1):S92. 7. Mariotto A, Jayasekerea J, Petkov V, et al. Expected monetary impact of Oncotype DX score-concordant systemic breast cancer therapy based on the TAILORx trial [published online ahead of print April 24, 2019]. *J Natl Cancer Inst*. doi:10.1093/jnci/djz068. 8. Centers for Medicare & Medicaid Services. Decision memo for next generation sequencing (NGS) for Medicare beneficiaries with advanced cancer (CAG-00450R). Published January 27, 2020. Accessed October 22, 2020. <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=296>

