

Biomarkers and Precision Oncology: What You Need to Know

The Role of Biomarkers in Cancer Care

Prognostic biomarkers



may not be linked to or trigger specific therapeutic decisions but aim to inform physicians regarding the aggressiveness or degree to which a cancer has advanced or its potential for recurrence.^{1,2}

Predictive biomarkers



predict response to specific therapeutic interventions. This can assist in the selection of patients likely to respond to a therapeutic.^{1,2}

Companion diagnostics



can be a diagnostic test or imaging tool that provides information essential for safe and effective use of a corresponding therapeutic product.^{2,3}

The Potential of Biomarkers^{1,2,4,5}

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



Identify

patients who would benefit most from treatment



Influence

treatment utilization



May **improve** treatment cost effectiveness

Key Genetic Biomarker Terminology

Precision oncology—the evolving understanding of how cancers develop at a genomic level and our ability to develop drugs that hone in on those targets, ultimately leading to better patient outcomes

Next-generation sequencing (NGS)—technologies that enable the rapid generation of data by their ability to sequence massive amounts of DNA in parallel using diverse methodologies^{5,6}

Basket trials—review patients regardless of tumor type and define treatment according to biomarkers^{7,8}

Liquid biopsy—the application of NGS to circulating tumor DNA (ctDNA) from a patient blood sample⁹

Biomarkers Are a Key Tool in the Implementation of Precision Oncology Identifying Patients

Percentage of patients whose tumors were driven by certain genetic mutations that could be targets for specific drugs by types of cancer^{10,11}

	Melanoma	73%		Breast	32%
	Thyroid	56%		Other gynecological	31%
	Colorectal	51%		Genitourinary	29%
	Endometrial	43%		Other gastrointestinal	25%
	Lung	41%		Ovarian	21%
	Pancreatic	41%		Head and neck	21%

Influencing Utilization

 **94** Oncology drugs specify at least 1 biomarker in their FDA label as of February 2020.¹²

Improving Cost Effectiveness With NGS

Annual estimated cost savings per 1 million members

\$2.1M Medicare¹³ & **\$250k** Commercial¹³

Coverage

Centers for Medicare and Medicaid Services now covering FDA-approved NGS companion diagnostics¹⁴

- FoundationOne® CDx
- MSK-IMPACT
- Oncomine™ Dx Target Test

For a copy of *The Precision Oncology Annual Trend Report*, Sixth Edition, contact your Novartis representative.



FDA, US Food and Drug Administration.

References: **1.** World Health Organization. Biomarkers in risk assessment: validity and validation. <http://www.inchem.org/documents/ehc/ehc/ehc222.htm>. Accessed May 20, 2020. **2.** Goossens N, Nakagawa S, Sun X, Hoshida Y. Cancer biomarker discovery and validation. *Transl Cancer Res.* 2015;4(3):256-269. **3.** US Food and Drug Administration. Companion diagnostic devices (in vitro imaging tools). <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm>. Accessed May 20, 2020. **4.** Schneider JE, Sidhu MK, Doucet C, Kiss N, Ohsfeldt RL, Chalfin D. Economics of cancer biomarkers. *Per Med.* 2012;9(8):829-837. **5.** American Association for Cancer Research. AACR cancer progress report. Philadelphia, PA: AACR; 2015. <http://www.cancerprogressreport-digital.org/cancerprogressreport/2015>. Accessed May 20, 2020. **6.** Center for Medical Terminology Policy. Initial medical policy and model coverage guidelines for clinical next generation sequencing in oncology. http://www.cmt.pnet.org/docs/resources/Full_Release_Version_August_13_2015.pdf. Accessed May 20, 2020. **7.** Memorial Sloan Kettering Cancer Center. Clinical trial shows promise of "basket studies" for cancer drugs. <https://www.mskcc.org/blog/clinical-trial-shows-promise-basket-studies-drugs>. Accessed May 20, 2020. **8.** National Cancer Institute. NCI Dictionary of Cancer Terms. Basket trial. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/797057>. Accessed May 20, 2020. **9.** Elazezy M, Joosse SA. Techniques of using circulating tumor DNA as a liquid biopsy component in cancer management. *Comput Struct Biotechnol J.* 2018;16:370-378. **10.** Personalized Medicine Coalition. The case for personalized medicine. http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/pmc_the_case_for_personalized_medicine.pdf. Accessed May 20, 2020. **11.** Winslow R. Major shift in war on cancer. *Wall Street Journal.* June 5, 2011. <https://www.wsj.com/articles/SB10001424052702304432304576367802580935000>. Accessed August 12, 2020. **12.** Center for Drug Evaluation and Research. Table of pharmacogenomic biomarkers in drug labeling. US Food and Drug Administration website. <https://www.fda.gov/drugs/science-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling>. Updated February 5, 2020. Accessed May 20, 2020. **13.** American Society of Clinical Oncology. Upfront, comprehensive genetic testing in advanced lung cancer is cost-effective. <https://www.asco.org/about-asco/press-center/news-releases/upfront-comprehensive-genetic-testing-advanced-lung-cancer>. Published May 16, 2018. Accessed May 20, 2020. **14.** US Food and Drug Administration. FDA Fact Sheet. CDRH's approach to tumor profiling next generation sequencing tests. <https://www.fda.gov/media/109050/download>. Accessed May 20, 2020.

