

# Cancer Biomarker Testing

*The key to unlocking precision cancer therapy.*

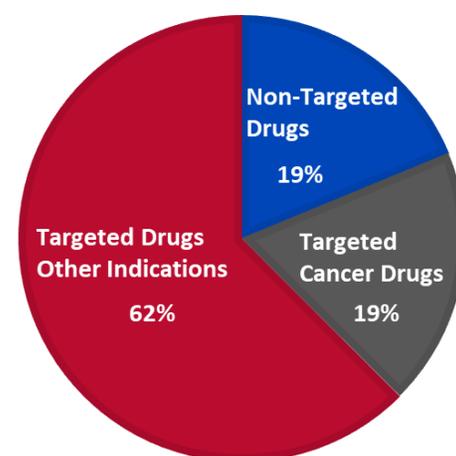


Progress in improving cancer outcomes increasingly involves the use of **precision medicine**, an approach that uses information about a person's own genes or proteins to prevent, diagnose, or treat disease. Advances in precision medicine in cancer have led to **targeted therapies** that only work within populations of cancer patients with very specific **biomarkers**, the biological molecules found in blood, tissues, or other bodily fluids that provide insight into physiological processes, medical conditions, or diseases.<sup>1</sup> Over the last several years there has been a rapid increase in the development of new targeted therapies across cancer types and diagnostics that help determine benefits from a specific therapy.

For example, in 2019:

- Targeted cancer therapies accounted for **about a quarter** of the targeted drug approvals by the U.S. Food and Drug Administration (FDA).<sup>2</sup>
- Cancer therapies made up **30% of the late-stage development pipeline**, primarily driven by targeted therapies.<sup>3</sup>
- **FDA approved the third tissue-agnostic targeted therapy** which can be used to treat cancer types that have the same genetic biomarker regardless of where the cancer starts in the body.<sup>4</sup>
- FDA approved or cleared **seven new diagnostics** that help identify patients for targeted therapy.<sup>5</sup>

## FDA-APPROVED NOVEL DRUGS IN 2019



New targeted cancer therapies have improved outcomes and quality of life across cancer types. Testing patients for cancer biomarkers, specifically the unique mutations of a cancer, is integral to identify those who may benefit from targeted therapy. Despite the importance of such testing, many cancer patients are not getting guideline-indicated biomarker testing of their tumors. For example, this spring, ACS CAN fielded several surveys (Survivor Views) to a cohort of more than 3,000 cancer survivors. The survey found:

**Only 39%** of respondents reported having their tumor tested.



**About 1 in 8** respondents indicated that biomarker testing was not covered by their insurer.



**15%** of respondents who received biomarker testing indicated that they had paid **\$500 or more out-of-pocket** for their testing.



As precision medicine shifts the way health care providers and patients think about cancer treatments, it will be important to identify barriers to biomarker testing. Addressing these barriers will require buy-in from diverse stakeholders across the health care system.

<sup>1</sup> NCI Dictionary of Cancer Terms. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/biomarker>. Accessed July 9, 2020.

<sup>2</sup> Wang, W., Sun, Q. Novel targeted drugs approved by the NMPA and FDA in 2019. *Sig Transduct Target Ther* 5, 65 (2020). <https://doi.org/10.1038/s41392-020-0164-4>

<sup>3</sup> 2019 R&D Achievements IQVIA Institute. Retrieved from: <https://www.iqvia.com/insights/the-iqvia-institute/reports/2019-r-and-d-achievements>

<sup>4</sup> New Drug Therapy Approvals 2019. <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/new-drug-therapy-approvals-2019#new>. Accessed July 13, 2020.

<sup>5</sup> Personalized Medicine at FDA The Scope and Significant Progress in 2019. Retrieved from: [http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PM at FDA The Scope and Significance of Progress in 2019.pdf](http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PM%20at%20FDA%20The%20Scope%20and%20Significance%20of%20Progress%20in%202019.pdf)