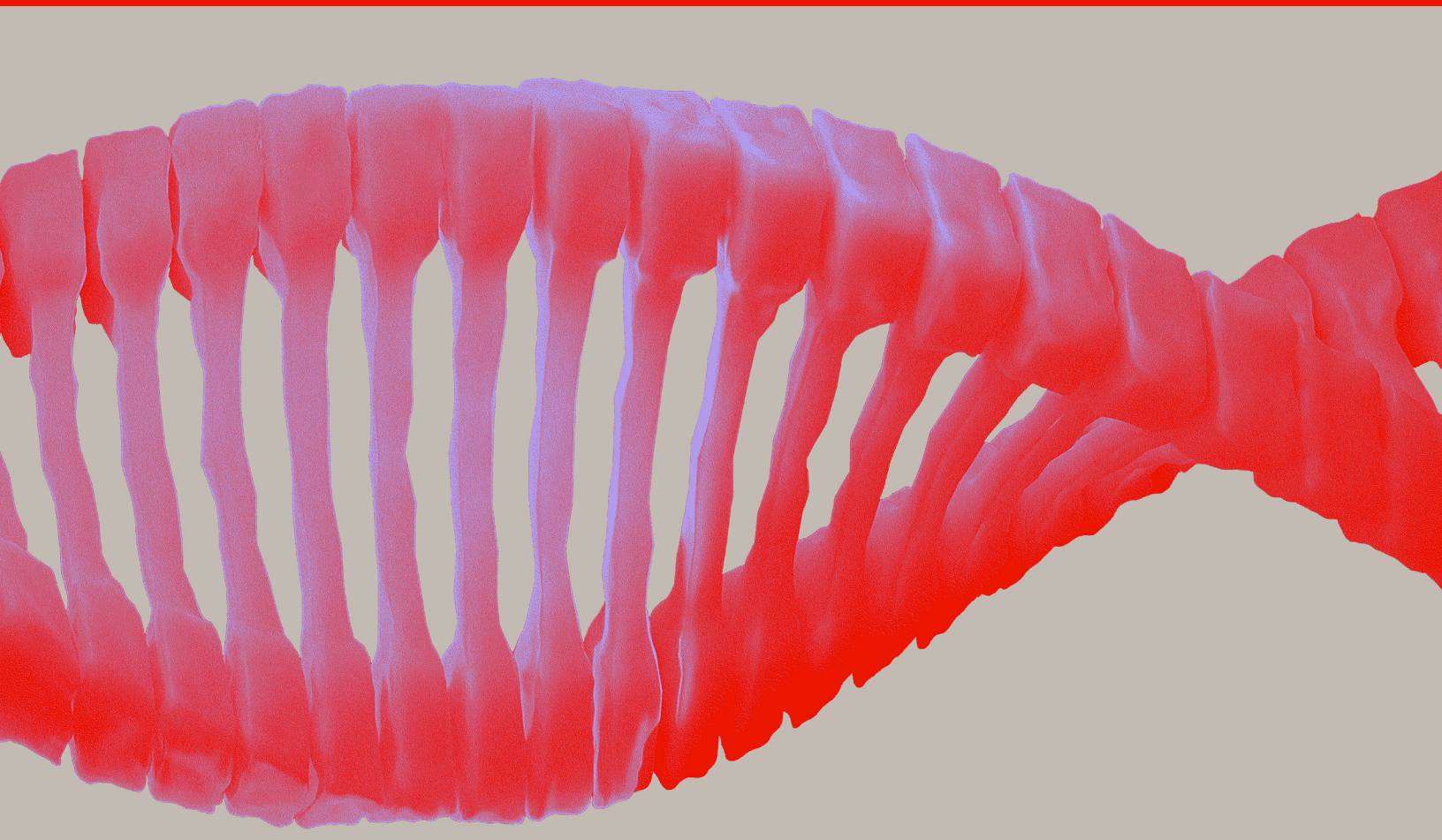
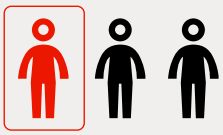
Biomarker Testing:

Considerations for Payer Coverage and Reimbursement

J&J
Precision Medicine

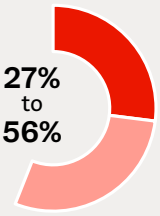


While many patients are eligible for biomarker-informed therapy, many do not receive testing[1–8]



~1 out of every 3
patients with cancer are **eligible for biomarker-informed treatment**[1,2]

In 1 large, retrospective study, multigene next-generation sequencing panel biomarker testing rates in advanced cancers range from[3]**:**



Many patients with advanced cancer* do not receive biomarker-informed care because they are **not tested**[3–8]

Access and reimbursement are considered significant barriers to testing, which can lead to negative healthcare outcomes[9–11]

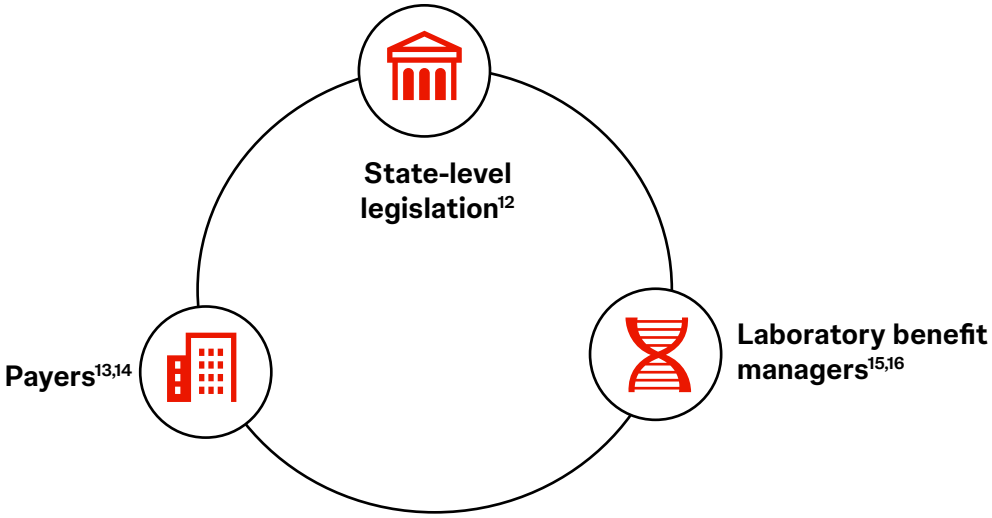
Findings from real-world data

Insurance coverage often plays a major role in how providers decide to test	**47.3%**	of providers reported that patients' insurance coverage was very important regarding the clinician's treatment decision to recommend genomic testing[9] According to the 2017 National Survey of Precision Medicine in Cancer Treatment.
Coverage of biomarker testing is inconsistent and even inadequate	**2/3**	of oncologists reported that their patients face significant or moderate insurance barriers in accessing biomarker testing[10] According to a 2021 survey conducted by the American Cancer Society.
Barriers in coverage can lead to patient dropoff	**29%**	of patients† did not have testing done due to lack of insurance coverage or because they could not afford the out-of-pocket costs[11] According to a 2019 survey conducted by the American Cancer Society.

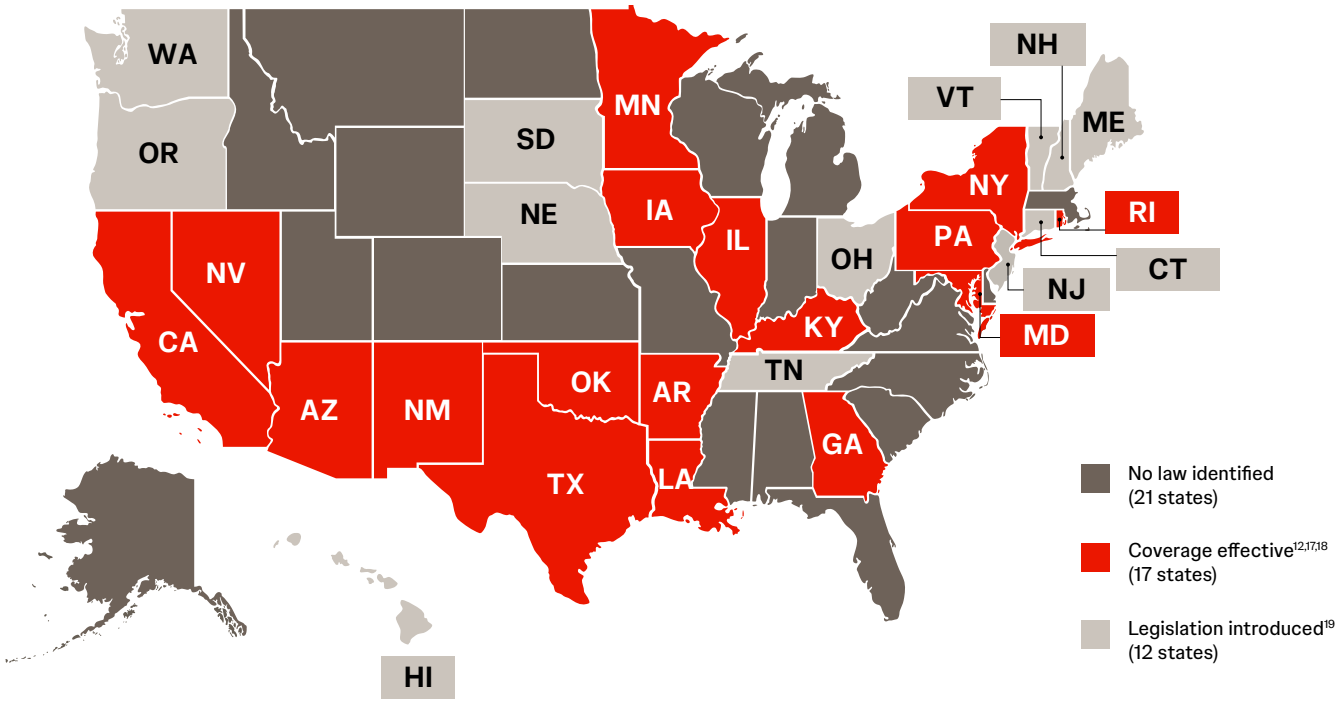
*Including non-small cell lung, ovarian, colorectal, breast, gastric, and prostate cancers.[3–8]
†Among those who discussed biomarker testing but did not get tested.[11]

Many factors impact coverage for biomarker testing[12–16]

Coverage policies and reimbursement dynamics for testing are influenced by:



Many states are passing legislation to expand access to biomarker testing[12,17–19]*



*As of February 2025.

Overview of biomarker testing laws

At least 17 states...

AZ AR CA GA IL IA KY LA
MD MN NV NM NY OK PA RI TX

...have adopted laws requiring Medicaid and/or private plans to cover biomarker testing under specific circumstances, and the number of state biomarker laws is growing over time[12,17,18]

All 17 states require coverage of testing based on if any of the following are met:

- FDA-approved labels for drugs (indicating testing required) or for tests (indicated conditions)[12,17,18]
- Medicare Coverage Determinations by CMS or Medicare Administration Contractor[12,17,18,20]
- Nationally recognized clinical practice guidelines[12,17,18]

Most state biomarker laws adopt or adapt suggested language from the American Cancer Society Cancer Action Network (ACS CAN) or National Council of Insurance Legislators (NCOIL)[21,22]

Note: ACS language aims to ensure patients have access to biomarker testing[23]

The vast majority of biomarker laws apply to private plans and Medicaid[12]

Laboratory benefit managers (LBMs) help manage biomarker testing for payers[15,16]

LBMs are intermediaries that manage multiple aspects of biomarker testing for payers[15,16]

LBMs

Offer a suite of services to help payers manage testing services[15,16]

LBM services include[16]:

- Medical necessity determinations
- Determining and enforcing medical and coverage policies
- Obtaining prior authorization
- Claims review
- Utilization review

Payers

Help guide treatment decisions through utilization management to optimize quality and cost[24]

Pay reimbursement for services rendered[25]

Provide insurance coverage by paying for covered services (wholly or partially)[25]

Providers and clinicians

Patients

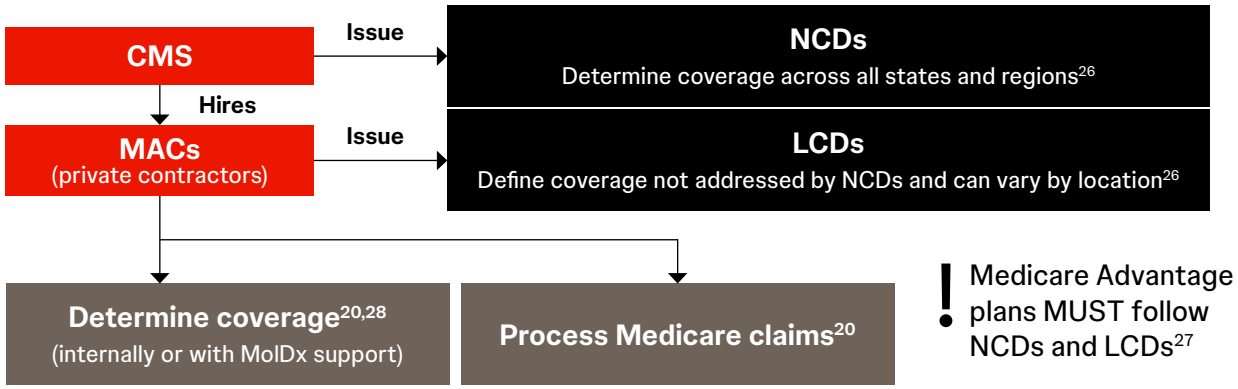
Directly provide care and make treatment decisions[25]

Did you know?

LBMs may improve biomarker testing payment turnaround times, but have the potential to increase prior authorization denials[16]

LBMs work alongside payers to manage coverage, utilization, and reimbursement of biomarker and genetic tests, often becoming equally influential in access[16]

National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) set forth coverage decisions for Medicare & Medicare Advantage policies[26,27]



MolDx is a program created by Palmetto GBA (a MAC) to:

- Determine if a molecular diagnostic test is reasonable and necessary under NCDs or LCDs[28]
- Enforce coverage criteria by assigning unique test identifiers, known as DEX Z-codes to molecular tests[28]
- Generate LCDs and/or article to support decision for contracted MACs[28]

MACs' Jurisdictions:

Palmetto GBA[28]
- Jurisdiction M: NC, SC, VA, WV
- Jurisdiction J: AL, GA, TN

Noridian Healthcare Solutions[28]
- Jurisdiction E : CA, NV, HI, American Samoa, Guam, Northern Mariana Islands
- Jurisdiction F : AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY

WPS Government Health Administrators[28]
- Jurisdiction 5: IA, KS, MO, NE
- Jurisdiction 8: IN, MI

CGS Administrators, LLC[28]
- Jurisdiction 15: KY, OH

National Government Services[29,30]
- Jurisdiction 6: IL, MN, WI
- Jurisdiction K: CT, MA, ME, NH, NY, RI, VT

Novita's Solutions, Inc.[31,32]
- Jurisdiction H: AR, CO, LA, MS, NM, OK, TX
- Jurisdiction L: DE, MD, NJ, PA, Washington D.C.

First Coast Service Options[33]
- Jurisdiction N: FL, Puerto Rico, U.S. Virgin Islands

Key factors to consider for biomarker testing reimbursement

Test type	Is the test FDA-approved?	Payers are more likely to cover FDA-approved tests with companion diagnostic indications[34]
Tumor type	Does the tumor potentially have actionable biomarkers?	Payers are more likely to cover testing for biomarkers included in clinical guidelines[34]
	Is tissue stewardship challenging?	Payer coverage of liquid biopsies is more likely when: • There is insufficient tissue for molecular analysis[34] • The patient is medically unfit for invasive tissue biopsy[34]
Test size	How many different genes is the panel able to detect?	Payer coverage of targeted multigene panels (<50 genes) is expanding due to: • More FDA-approved biomarker-informed therapies[34] • Recognition of efficiency and cost-effectiveness[34] Payer coverage of large multigene panels (>50 genes) remains limited[34] Coverage for LDTs varies. Check with payer plans[35]
Insurance type	Who is the insurance provider?	Reimbursement and out-of-pocket costs vary by insurance plan and provider[13,14] **Prior authorization requirements** are determined by the provider and **may delay testing**[14]
Test logistics	When and where will the test be performed?	The type of test, timing of testing, and whether biopsy was collected in the inpatient, outpatient, or non-hospital setting determine Medicare coverage based on the 14-day rule[36]

Did you know?

Biomarker testing is reimbursed by insurance companies independent of the FDA-approved therapy or treatment[36]

The 14-day rule dictates how testing is reimbursed for Medicare patients[36]

The 14-day rule[36]*:

Diagnostic testing ordered <14 days after **inpatient** discharge must be billed to the hospital

Testing for **non-hospital patients** should be billed to Medicare regardless of test date

Key definitions for the 14-day rule:

Inpatient[37]	Outpatient[37]	Non-hospital patient[38]
Patients admitted to the hospital per physician's order The last inpatient day is considered the day before discharge	**Patients receiving services, treatments, or tests with no hospital admission**	Patients biopsied at a private office or commercial laboratory who **did not visit the hospital on the date of biopsy**

Under the 14-day rule, billing is based on test ordered date, care setting, and test type[36]

		Hospital inpatient	Discharged from hospital	Non-hospital patient
<14 days from discharge	Exempt tests† are billed to:	Hospital	**Medicare** (if performed in outpatient setting)	Outside of the 14-day rule
	Non-exempt tests are billed to:	Hospital	Hospital	**Medicare**
≥14 days from discharge	Exempt tests are billed to:	**Medicare**	**Medicare**	
	Non-exempt tests are billed to:	**Medicare**	**Medicare**	

Laboratories can bill Medicare in ~75% of possible testing scenarios[36]

*The 14-day rule is also known as the Laboratory Date of Service Policy.

†Exempt tests include advanced diagnostic laboratory tests (ADLTs), cancer-related protein-based multi-analyte algorithmic assays (MAAAs), and molecular pathology tests except for IHC, FISH, and immunoassay.

Some diagnostic tests are exempt from the 14-day rule and may be billed to Medicare[36]

Exemptions to the 14-day rule[36]

The following may be exempt for patients who were discharged from the hospital within 14 days:

- Molecular pathology tests*
- Advanced diagnostic laboratory tests (ADLTs)
- Cancer-related protein-based multi-analyte algorithmic assays (MAAAs)

Centers for Medicare & Medicaid Services provides a list of laboratory test codes subject to exception available at: **www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/date-service-policy**

Examples where testing is billed to the hospital when ordered <14 days from discharge[36]:

Inpatients	or	Certain testing methods
The 14-day rule **always applies** in the inpatient setting		Methods such as **FISH, IHC, and immunoassays** are not exempt

Did you know?

The 14-day rule does not apply to commercially insured patients[36]

*IHC, FISH, and immunoassay are not exempt from the 14-day rule and must be billed to the hospital if performed less than 14 days from outpatient discharge.

Summary

Although 1 in 3 patients with cancer are eligible for biomarker testing, many do not receive it[1–8]

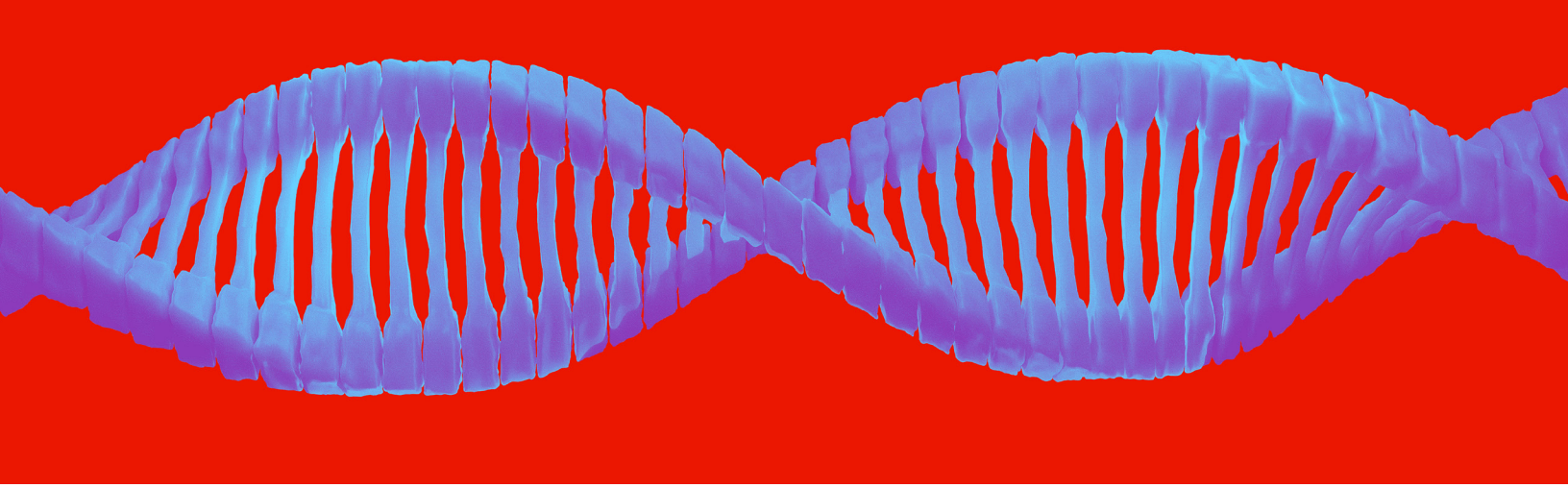
While payer coverage is expanding, access and reimbursement are considered significant barriers to biomarker testing[10,34]

Key factors to consider for biomarker testing reimbursement include the test type, tumor type, test size, and the 14-day rule[34,36]

The 14-day rule states that diagnostic testing for Medicare patients ordered <14 days after inpatient or outpatient discharge must be billed to the hospital[36]

ACS, American Cancer Society; ACS CAN, American Cancer Society Cancer Action Network; ADLT, advanced diagnostic laboratory test; CMS, Centers for Medicare & Medicaid Services; FDA, U.S. Food and Drug Administration; FISH, fluorescence in situ hybridization; IHC, immunohistochemistry; LBM, laboratory benefits manager; LCD, local coverage determination; LDT, laboratory-developed test; MAAA, multi-analyte algorithmic assay; MAC, Medicare administrative contractor; MolDX, Molecular Diagnostic Services Program; NCD, national coverage determination; NCOIL, National Council of Insurance Legislators.

References: 1. Suehnholz SP, Nissan MH, Zhang H, et al. Quantifying the expanding landscape of clinical actionability for patients with cancer. *Cancer Discov.* 2024;14(1):49–65. **2.** Chakravarty D, Solit DB. Clinical cancer genomic profiling. *Nat Rev Genet.* 2021;22(8):483–501. **3.** Byfield SD, Bapat B, Becker L, et al. Real-world analysis of commercially insured and Medicare Advantage patients with advanced cancer and rates of molecular testing. *J Clin Oncol.* 2023;41(suppl 16):abstract 6633. **4.** Hage Chehade C, Jo Y, Gebrael G, et al. Trends and disparities in next-generation sequencing in metastatic prostate and urothelial cancers. *JAMA Netw Open.* 2024;7(7):e2423186. doi:0.1001/jamanetworkopen.2024.23186 **5.** Baron JM, Widatalla S, Gubens MA, et al. Real-world biomarker test ordering practices in non–small cell lung cancer: interphysician variation and association with clinical outcomes. *JCO Precis Oncol.* 2024;8:e2400039. doi:10.1200/PO.24.00039 **6.** Gordan LN, Diaz M, Patel AJ, et al. Effective biomarker testing rates in a large U.S. community practice. *J Clin Oncol*. 2022;40(suppl 16):abstract e21093. **7.** Sabbagh S, Herrán M, Hijazi A, et al. Biomarker testing disparities in metastatic colorectal cancer. *JAMA Netw Open.* 2024;7(7):e2419142. doi:10.1001/jamanetworkopen.2024.19142 **8.** Robinson HR, Hu J, Balmaceda NB, et al. Disparities and trends in biomarker testing in metastatic colorectal cancer. *J Clin Oncol.* 2024;42(suppl 3):abstract 29. **9.** Yabroff KR, Sylvia Shi K, Zhao J, et al. Importance of patient health insurance coverage and out-of-pocket costs for genomic testing in oncologists' treatment decisions. *JCO Oncol Pract.* 2024;20(3):429–437. **10.** American Cancer Society: Cancer Action Network. Accessed February 21, 2025. https://www.fightcancer.org/sites/default/files/national_documents/provider_utilization_of_biomarker_testing_polling_memo_dec_2021.pdf **11.** American Cancer Society: Cancer Action Network. Accessed February 21, 2025. https://www.fightcancer.org/sites/default/files/Survivor%20Views%20Biomarker%20Testing%20Polling%20Memo.pdf **12.** Lin GA, Coffman JM, Phillips KA. The state of state biomarker testing insurance coverage laws. *JAMA*. 2024;331(22):1885–1886. **13.** Wong WB, Anina D, Lin CW, et al. Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors. *Per Med.* 2022;19(3):171–180. **14.** Sadigh G, Goeckner HG, Kazerooni EA, et al. State legislative trends related to biomarker testing. *Cancer.* 2022;128(15):2865–2870. **15.** Douglas MP, Ragavan MV, Chen C, et al. Private payer and Medicare coverage policies for use of circulating tumor DNA tests in cancer diagnostics and treatment. *J Natl Compr Canc Netw.* 2023;21(6):609–616.e4. **16.** Cohen P. The time is now for laboratory benefit management. *MHE*. 2022;32(4). Accessed February 21, 2025. https://www.managedhealthcareexecutive.com/view/the-time-is-now-for-laboratory-benefit-management **17.** Bill Track 50. Accessed February 7, 2025. https://www.billtrack50.com/billdetail/1724776 **18.** Bill Track 50. Accessed February 7, 2025. https://www.billtrack50.com/billdetail/1644508 **19.** Legiscan. Accessed February 6, 2025. https://legiscan.com/gaits/search?sort=desc&order=State&state=ALL&keyword=biomarker **20.** Centers for Medicare & Medicaid Services. Accessed February 21, 2025. https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/whats-mac **21.** Peck K, Pack J. The long and winding road of biomarker legislation. *GIM Open.* 2024;2(suppl 1):abstract P882. **22.** NCOIL Adopts Two New Health Insurance Model Laws At Summer Meeting In Minneapolis 2023. Accessed February 7, 2025. https://ncoil.org/wp-content/uploads/2023/08/NCOIL-Adopts-Two-New-Health-Insurance-Model-Laws-at-Summer-Meeting-in-Minneapolis-8-7-2023.pdf **23.** Fox AH, Osarogiagbon RU, Farjah F, et al. The American Cancer Society National Lung Cancer Roundtable strategic plan: advancing comprehensive biomarker testing in non-small cell lung cancer. *Cancer.* 2024;130(24):4188–4199. **24.** Institute of Medicine (US) Committee on Utilization Management by Third Parties, Gray BH, Field MJ. *Controlling costs and changing patient care? The role of utilization management.* Accessed February 7, 2025. https://www.ncbi.nlm.nih.gov/books/NBK235003/ **25.** Panoramic Health. The Difference Between Healthcare Payers and Providers. Accessed February 7, 2025. https://panoramichealth.com/blog/the-difference-between-healthcare-payers-and-providers/ **26.** Centers for Medicare & Medicaid Services. Accessed February 21, 2025. https://www.cms.gov/medicare-coverage-database/help/Document_Type_Descriptions.pdf?t=638421557436962248#:~:text=LCD,the%20Proposed%20LCD%20development%20process **27.** CMS Newsroom. Accessed February 7, 2025. https://www.cms.gov/newsroom/fact-sheets/contract-year-2026-policy-and-technical-changes-medicare-advantage-program-medicare-prescription **28.** Palmetto GBA. Accessed February 6, 2025. https://www.palmettogba.com/Palmetto/moldx.Nsf/files/MolDX_Manual.pdf/$File/MolDX_Manual.pdf?Open& **29.** Centers for Medicare & Medicaid Services. Accessed February 6, 2025. https://www.cms.gov/medicare/medicare-contracting/medicare-administrative-contractors/who-are-the-macs-a-b-mac-jurisdiction-6-j6 **30.** Centers for Medicare & Medicaid Services. Accessed February 6, 2025. https://www.cms.gov/medicare/medicare-contracting/medicare-administrative-contractors/who-are-the-macs-a-b-mac-jurisdiction-k-jk **31.** Centers for Medicare & Medicaid Services. Accessed February 6, 2025. https://www.cms.gov/medicare/medicare-contracting/medicare-administrative-contractors/who-are-the-macs-a-b-mac-jurisdiction-h-jh **32.** Centers for Medicare & Medicaid Services. Accessed February 6, 2025. https://www.cms.gov/medicare/medicare-contracting/medicare-administrative-contractors/who-are-the-macs-a-b-mac-jurisdiction-l-jl **33.** Centers for Medicare & Medicaid Services. Accessed February 6, 2025. https://www.cms.gov/medicare/medicare-contracting/medicare-administrative-contractors/who-are-the-macs-a-b-mac-jurisdiction-n-jn **34.** American Cancer Society. Accessed February 21, 2025. https://www.fightcancer.org/policy-resources/payer-coverage-policies-tumor-biomarker-and-pharmacogenomic-testing **35.** NIH SEED Innovator Support Team. Accessed February 21, 2025. https://seed.nih.gov/sites/default/files/2024-04/Reimbursement-Knowledge-Guide-for-Diagnostics.pdf **36.** Centers for Medicare & Medicaid Services. Accessed February 21, 2025. https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/date-service-policy **37.** Medicare. Accessed February 21, 2025. https://www.medicare.gov/coverage/inpatient-hospital-care/inpatient-outpatient-status **38.** CMS Manual System. Accessed February 21, 2025. https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r2971cp.pdf



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