

The majority of NSCLC patients have coverage for next-generation sequence (NGS) testing^{1,2}

Check your patient's insurance to determine which test is

Coverage Status for NGS in Major National Plans* for non-small cell lung cancer (NSCLC), as of August 2020; please complete a benefit verification to assess the coverage of specific tests

Health Plans		FDA-APPROVED				MSK-IMPACT (CPT: 0048U) ⁴	Panels 5-50 Genes (CPT: 81445) [†]	Panels >50 Genes (CPT: 81455) [†]
		Oncomine Dx Target Test (CPT: 0022U) ²²	FoundationOne CDx (CPT: 0037U) ²²	FoundationOne Liquid CDx (CPT: 0239U) ²¹	Guardant360 (Liquid) (CPT: 81479) ²³			
Commercial	Anthem ^{4,5,4,9}	✓	⊙	⊙	⊙	⊙	✓	⊙
	Aetna ^{6-7,**,††}	✓	⊙	⊙	⊙	✓	✓	⊙
	Cigna ^{11-12,‡,§§,***,†††}	✓	—	✓	✓	✓	⊙	—
	Humana ^{13-15,††}	—	⊙	⊙	⊙	⊙	⊙	⊙
Medicare ¹⁶ Original Medicare & Medicare Advantage ^{20,†††}	NCD ² (Only covers FDA approved tests)	✓	✓	✓	✓	N/A	N/A	N/A
	LCD ^{17-19,§§§}	N/A	N/A	N/A	N/A	✓	~ Vary across MACs and Plans	~ Vary across MACs and Plans

✓ Covered

⊙ Not Covered

— Not Specified

N/A Not Applicable

CPT=Current Procedural Terminology; NCD=National Coverage Determination; LCD=Local Coverage Determination; MAC=Medicare Administrative Coordinator.

*Commercial health plans are selected as they represent the largest national payers in the US. Tests are selected to include tests and codes that are specifically listed in national plans, however, this may not be a comprehensive list, nor an endorsement to use any specific test. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. In no way should the information provided in this document be considered a guarantee of coverage or reimbursement for any product or service. †CPT codes 81445 and 81455 represent testing for procedures on "solid organ or hematolymphoid neoplasms"²³ ‡Considered medically necessary if testing is used to assess "tumor mutation burden and identify candidates for checkpoint inhibition immunotherapy."⁴ §81445 listed as "may be covered" and "investigational"; coverage varies if patient and test meet medical criteria.⁴ **Aetna may cover tests via additional partnership programs, such as CVS-Tempus partnership (Transform Oncology Care™), a program available in 12 states for Tempus xT tests, although as of Aug. 2020, Tempus xT was not listed explicitly in Aetna's medical policy.^{6,8-10} ††Humana and Aetna cover FoundationOne CDx for some ovarian cancer patients^{7,13}; Aetna covers FoundationOne CDx for men with metastatic castration-resistant prostate cancer.⁷ †††Cigna's policy explicitly lists 81445 as not covered; policy does not include 81455.¹¹ §§Considered medically necessary when used for the identification of BRAF600E mutations for Tafenlar+Mekinist and ROS fusions for Xalkori.¹² ***Considered medically necessary for identification of EGFR exon 19 deletions for Iressa.¹² ††††Considered medically necessary if tissue sample is not available or at progression on EGFR tyrosine kinase inhibitors.¹² †††††Medicare Advantage sponsors may issue their own policy in the absence of NCDs or LCDs.²⁰ §§§For laboratory tests performed at a single location, the MAC jurisdiction will be based on the state in which the performing lab is located.¹⁹ National Government Services, a MAC with jurisdiction over New York State, issued an LCD covering



Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Always check your patient's insurance to select a covered

Steps to Support Coverage for NGS Biomarker

01

Benefit Verification²⁴

Patient's insurance coverage is confirmed

02

Prior Authorization (PA)^{24,25}

(not all insurers or tests require)

PA form and supporting materials submitted to insurance company

03

NGS Test Ordered²⁴

Provider orders biomarker test

04

NGS Test Performed²⁴

Lab performs test

05

NGS Test Results Stored²⁸

Ensure test results are available to support treatment coverage

Potential PA Information

- Patient diagnosis or clinical indication
- CPT code and NGS test name
- Reason for testing/how test results will inform treatment
- Laboratory studies and results
- Prior treatments or clinical findings
- Date that the test was performed or is anticipated to be

*Directional only; please complete a benefit verification to assess the coverage and prior authorization requirement of specific tests. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. In no way should the information provided in this document be considered a guarantee of coverage or reimbursement for any product or service.

References 1. Data on File. 2. Food and Drug Administration. Updated September 10, 2020. <https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools> 3. UnitedHealthcare Provider. Accessed August 2020. <https://www.uhcprovider.com/content/provider/en/viewer.html?file=https%3A%2F%2Fwww.uhcprovider.com%2Fcontent%2Fdam%2Fprovider%2Fdocs%2Fpublic%2Fcomm-medical-drug%2Fmolecular-oncology-testing-for-cancer.pdf> 4. Anthem. Published July 8, 2020. Accessed August 2020. https://www.anthem.com/dam/medpolicies/abcbs/active/policies/mp_pw_e000224.html 5. Anthem. Published July 1, 2020. Accessed August 2020. https://www.anthem.com/dam/medpolicies/abcbs/active/policies/mp_pw_d082650.html 6. Aetna. Accessed August 2020. http://www.aetna.com/cpb/medical/data/300_399/0352.html 7. Aetna. Accessed August 2020. http://www.aetna.com/cpb/medical/data/700_799/0715.html 8. Tempus. Published December 12, 2019. Accessed August 2020. <https://www.tempus.com/cvs-health-launches-transform-oncology-care-program-to-help-improve-patient-outcomes-and-lower-overall-costs/> 9. Humer C, Steenhuisen J. Reuters. Published December 12, 2019. Accessed August 2020. <https://www.reuters.com/article/cvs-health-cancer/cvs-to-increase-genetic-testing-for-some-aetna-cancer-patients-idUSL1N28L1J5> 10. Tempus. Accessed August 2020. <https://www.tempus.com/billing-faqs/> 11. Cigna for Health Care Professionals. Accessed August 2020. https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm_0520_coveragepositioncriteria_tumor_profiling.pdf 12. Cigna for Health Care Professionals. Accessed August 2020. https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/Genetic_Testing_Collateral_Document.pdf 13. Humana. Accessed August 2020. http://apps.humana.com/tad/tad_new/Search.aspx?criteria=Osimertinib&searchtype=freetext&policyType=both 14. Humana. Accessed August 2020. http://apps.humana.com/tad/tad_new/Search.aspx?criteria=molecular+testing&searchtype=freetext&policyType=both 15. Humana. Accessed August 2020. http://apps.humana.com/tad/tad_new/Search.aspx?criteria=liquid+biopsy&searchtype=freetext&policyType=both 16. Centers for Medicare & Medicaid Services. Published January 27, 2020. <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=29617> 17. Centers for Medicare & Medicaid Services. Updated October 3, 2019. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37810&ver=8&DocType=4&bc=AgIAAAABAAAA&19> 18. Centers for Medicare & Medicaid Services. Updated October 3, 2019. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37810&ver=8&DocType=4&bc=AgIAAAABAAAA&19> 19. Centers for Medicare & Medicaid Services. Revised January 17, 2020. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf> 20. Centers for Medicare & Medicaid Services. Revised April 22, 2016. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf> 21. American Medical Association. Updated October 6, 2020. Accessed October 22, 2020. <https://www.ama-assn.org/system/files/2020-10/cpt-pla-codes-long.pdf> 22. Ferrera J, Sanderson ML. Accessed October 22, 2020. <https://cdn2.hubspot.net/hubfs/2758906/Navigation%20the%20Reimbursement%20Landscape%20for%20Clinical%20NGS%20Diagnostics.pdf> 23. United States Securities and Exchange Commission Filing March 2020. Accessed October 22, 2020. <https://investors.guardianhealth.com/node/7661/html> 24. Foundation Medicine. Published 2018. Accessed October 22, 2020. https://assets.ctfassets.net/w98cd481qyp0/PKWlTAZ3RTtdZcoyGn5/545686f783e61ff7823206676bd9d72b/Foundation_Medicine_Patient_Billing_Guidelines.pdf 25. Foundation Medicine. Accessed October 22, 2020. <https://www.foundationmedicine.com/resource/billing-and-financial-assistance> 26. Humana. Accessed October 22, 2020. <https://docushare-web.apps.cf.humana.com/Marketing/docushare-app?file=1986712.27> 27. Humana Molecular Testing Preauthorization Request. Published 2020. Accessed October 22, 2020. Humana.com. <https://www.humana.com/provider/medical-resources/authorizations-referrals?service=moleculardiagnostic/geneticTesting> 28. Kim ES, et al. J Thorac Oncol. 2019;14(3):338-342.



Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-
1799