

# KRAS G12C Testing

## Reimbursement and Access Guide

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KRAS G12C is one of the most prevalent biomarkers in NSCLC, occurring in 13% of non-squamous patients<sup>1</sup>

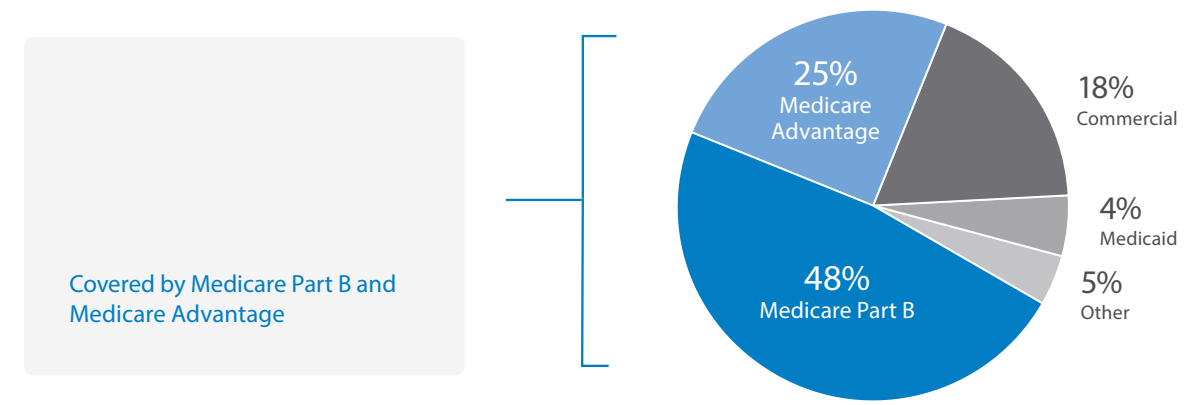


NSCLC = non-small cell lung cancer

Reference: 1. Data on file, Amgen; 2020.

# The majority of NSCLC patients will be covered for their biomarker tests<sup>1</sup>

## Estimated payer mix for NSCLC biomarker test<sup>1</sup>



## Most patients with NSCLC have insurance coverage for KRAS G12C biomarker testing<sup>1</sup>

NGS*		Single-Gene Tests**	
Commercially Insured Patients <sup>2-9</sup>	Medicare Patients <sup>10</sup>	Commercially Insured Patients <sup>2,5,11-14</sup>	Medicare Patients <sup>15</sup>
As of January 2021, 4 out of the 5 top national commercial payers cover at least 1 NGS test	All FDA-approved tests are covered through national coverage determination	Single-gene KRAS testing is covered by the top 5 national commercial payers	Single-gene KRAS testing is covered through all local coverage determinations

## Other factors that can impact the insurance coverage of biomarker tests

### Sample type

- Tissue-based biomarker tests - coverage generally broader<sup>3</sup>
- Liquid-based biomarker tests - coverage more selective<sup>16</sup>

### Regulatory status<sup>10</sup>

- FDA approval is not generally required for biomarker tests to be covered by payers<sup>10</sup>

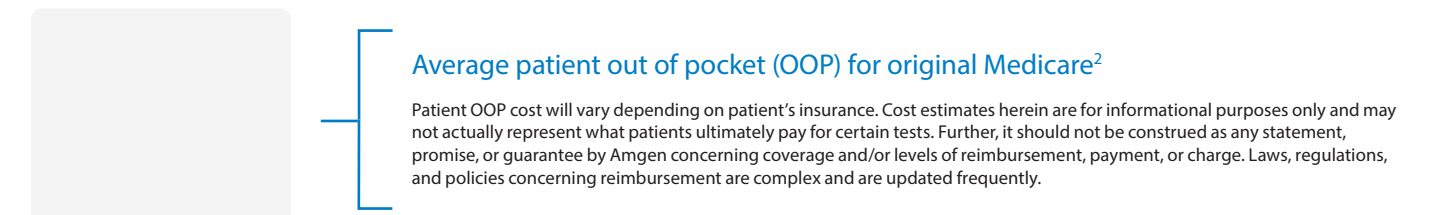
PCR = polymerase chain reaction; NGS = next generation sequencing

\*Claim is based on membership size.<sup>17</sup>

\*\*Payer coverage for KRAS tests may not be specific to NSCLC, and NSCLC-specific coverage is expected due to targeted therapy approval. LDT coverage varies by regional commercial payer and local Medicare contract administrator.

References: 1. Data on file for Metastatic NSCLC Payer Mix Solution. 2. Aetna. [www.aetna.com/cpb/medical/data/300\\_399/0352.html](http://www.aetna.com/cpb/medical/data/300_399/0352.html). Accessed December 2020. 3. Anthem. [www.anthem.com/dam/medpolicies/abcbs/active/policies/mp\\_pw\\_d082650.html](http://www.anthem.com/dam/medpolicies/abcbs/active/policies/mp_pw_d082650.html). Accessed December 2020. 4. Anthem. [www.anthem.com/dam/medpolicies/abc/active/policies/mp\\_pw\\_e000224.html](http://www.anthem.com/dam/medpolicies/abc/active/policies/mp_pw_e000224.html). Accessed December 17, 2020. 5. Humana. [apps.humana.com/tad/tad\\_new/Search.aspx?criteria=Osimertinib&searchtype=freetext&policyType=both](http://apps.humana.com/tad/tad_new/Search.aspx?criteria=Osimertinib&searchtype=freetext&policyType=both). Accessed January 7, 2021. 6. Humana. [apps.humana.com/tad/tad\\_new/Search.aspx?criteria=liquid+biopsy&searchtype=freetext&policyType=both](http://apps.humana.com/tad/tad_new/Search.aspx?criteria=liquid+biopsy&searchtype=freetext&policyType=both). Accessed January 7, 2021. 7. Humana. [apps.humana.com/tad/tad\\_new/Search.aspx?criteria=genetic+testing+for+diagnosis&searchtype=freetext&policyType=both](http://apps.humana.com/tad/tad_new/Search.aspx?criteria=genetic+testing+for+diagnosis&searchtype=freetext&policyType=both). Accessed January 7, 2021. 8. Tempus. [www.tempus.com/cvs-health-launches-transform-oncology-care-program-to-help-improve-patient-outcomes-and-lower-overall-costs](http://www.tempus.com/cvs-health-launches-transform-oncology-care-program-to-help-improve-patient-outcomes-and-lower-overall-costs). Accessed January 7, 2021. 9. United Healthcare. [www.uhcprovider.com/content/provider/en/viewer.html?file=https%3A%2F%2Fwww.uhcprovider.com%2Fcontent%2Fdam%2Fprovider%2Fdocs%2Fpublic%2Fpolicies%2Fcomm-medical-drug%2Fmolecular-oncology-testing-for-cancer.pdf](http://www.uhcprovider.com/content/provider/en/viewer.html?file=https%3A%2F%2Fwww.uhcprovider.com%2Fcontent%2Fdam%2Fprovider%2Fdocs%2Fpublic%2Fpolicies%2Fcomm-medical-drug%2Fmolecular-oncology-testing-for-cancer.pdf). Accessed January 7, 2021. 10. Center for Medicare and Medicaid Services. [www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=296](http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=296). Accessed December 17, 2020. 11. Anthem. [www.anthem.com/dam/medpolicies/abc/active/guidelines/gl\\_pw\\_d056639.html](http://www.anthem.com/dam/medpolicies/abc/active/guidelines/gl_pw_d056639.html). Accessed January 7, 2021. 12. Cigna. [cigna.com/public/content/pdf/coveragePolicies/medical/mm\\_0520\\_coveragepositioncriteria\\_tumor\\_profiling.pdf](http://cigna.com/public/content/pdf/coveragePolicies/medical/mm_0520_coveragepositioncriteria_tumor_profiling.pdf). Accessed January 7, 2021. 13. Cigna. [cigna.com/public/content/pdf/coveragePolicies/medical/mm\\_0520\\_coveragepositioncriteria\\_tumor\\_profiling.pdf](http://cigna.com/public/content/pdf/coveragePolicies/medical/mm_0520_coveragepositioncriteria_tumor_profiling.pdf). Accessed January 7, 2021. 14. QIAGEN. [www.qiagen.com/us/service-and-support/learning-hub/technologies-and-research-topics/oncology-companion-diagnostics/therascreen-kras-test-usa-labs](http://www.qiagen.com/us/service-and-support/learning-hub/technologies-and-research-topics/oncology-companion-diagnostics/therascreen-kras-test-usa-labs). Accessed January 11, 2021. 15. Center for Medicare and Medicaid Services. [www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56199&ver=36&bc=CAAAAAAAAAA](http://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56199&ver=36&bc=CAAAAAAAAAA). Accessed January 11, 2021. 16. Douglas MP, et al. *JNCCN*. 2020;18(7):866-872. 17. Schoen C, Collins SR. *Health Affairs*. 2017;36(12):2185-2194.

# Medicare coverage for biomarker tests are set nationally or locally<sup>1</sup>



National Coverage Determination (NCD)	Local Coverage Determination (LCD)
Set nationally by CMS	Set locally by MACs
Only one NCD covers FDA-approved NGS panels for patients with advanced cancer (stages III or IV) and, as of January 2021, four FDA-approved NGS panels have indications for NSCLC <sup>1,3,4</sup>	MACs may issue LCDs to establish coverage for NGS tests that are not covered through the NCD <sup>1</sup>
<ul style="list-style-type: none"> <li>• Oncomine Dx Target Test</li> <li>• Foundation One CDx</li> <li>• Foundation One Liquid CDx</li> <li>• Guardant360<sup>®</sup> CDx</li> </ul>	<ul style="list-style-type: none"> <li>• Single-gene tests (FDA-approved or not) and non-FDA approved NGS panels, which reflect the majority of KRAS G12C tests<sup>4-10</sup></li> </ul>

CMS = Centers for Medicare & Medicaid Services, a federal agency that administers the Medicare program and works in partnership with state governments to administer Medicaid. MAC = Medicare Administrative Contractors, private health insurers that manage Medicare claims for a specific region.

References: 1. Centers for Medicare & Medicaid Services. Published 2003. Accessed December 16, 2020. <https://www.govinfo.gov/content/pkg/FR-2003-09-26/pdf/03-24361.pdf>. 2. Centers for Medicare & Medicaid Services. Accessed December 24, 2020. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf>. 3. Centers for Medicare & Medicaid Services. Published January 27, 2020. <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=296>. 4. Food and Drug Administration. Updated December 16, 2020. <https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools>. 5. Trosman JR, et al. *Value in Health*. 2018; doi.org/10.1016/j.val.2018.06.011. 6. Foundation Medicine. Published 2020. Accessed December 16, 2020. [https://assets.ctfassets.net/w98cd481qyp0/YqqKHaqMFeq5ueQk48w/0a34fcd3a71d460c01cebe8ad/F1CDx\\_Technical\\_Specifications\\_072020.pdf](https://assets.ctfassets.net/w98cd481qyp0/YqqKHaqMFeq5ueQk48w/0a34fcd3a71d460c01cebe8ad/F1CDx_Technical_Specifications_072020.pdf). 7. ThermoFisher Scientific. Published 2020. Accessed December 17, 2020. <https://assets.thermofisher.com/TFS-Assets/LSG/brochures/oncomine-dx-target-test-brochure.pdf>. 8. Quest Diagnostics. Accessed December 17, 2020. <https://testdirectory.questdiagnostics.com/test/test-detail/16510/kras-mutation-analysis?cc=MASTER>. 9. Mayo Clinic Laboratories. Accessed December 17, 2020. <https://oncology.testcatalog.org/show/KRASO>. 10. NeoGenomics Test Catalog. Published 2020. Accessed December 17, 2020. <https://neogenomics.com/sites/default/files/neogenomics/NeoGenomicsTestCatalog.pdf>

# It is important to verify your patient's benefits as coverage for biomarker tests vary by commercial payer

## Average patient out of pocket for commercial insurance<sup>1</sup>

Patient OOP cost will vary depending on patient's insurance. Cost estimates herein are for informational purposes only and may not actually represent what patients ultimately pay for certain tests. Further, it should not be construed as any statement, promise, or guarantee by Amgen concerning coverage and/or levels of reimbursement, payment, or charge. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently.

## Typical steps to support coverage for biomarker tests

- 01 VERIFY BENEFITS<sup>2</sup>**  
Confirm patient's insurance coverage
- 02 MANAGE PRIOR AUTHORIZATION (PA)<sup>3</sup>**  
Submit PA form and supporting materials to insurance company (not all insurers or tests require)
- 03 ORDER TEST<sup>2</sup>**  
Provider orders biomarker test
- 04 PERFORM TEST<sup>2</sup>**  
Lab performs test
- 05 STORE TEST RESULTS<sup>5</sup>**  
Ensure test results are available to support treatment coverage

### POTENTIAL PA INFORMATION NEEDED<sup>4</sup>

- Patient diagnosis or clinical indication
- CPT code and test name
- Reason for testing/how test results will inform treatment
- Laboratory studies and results
- Prior treatments or clinical findings
- Anticipated date of test

# Sample billing and coding information for reimbursement

Many KRAS G12C biomarker tests are billed with Category I CPT codes, while some are billed with PLA codes<sup>1,2</sup>

Billing and coding errors could delay biomarker testing and impact the test reimbursement for providers and labs

Examples of CPT codes for select biomarker tests<sup>1-5</sup>

Sample type	Modality	Test name*	CPT code category	Code description	CPT codes
Tissue	PCR	Qiagen Therascreen KRAS	Category I	KRAS gene analysis	81275
	NGS	ThermoFisher OncoPrint	PLA	23 gene targeted genomic sequence panel	0022U
		FoundationOne CDx	PLA	DNA gene analysis of 324 genes in solid organ tumor tissue	0037U
Liquid	NGS	Guardant360 CDx	PLA	cell-free circulating DNA analysis of 55-74 genes	0242U
Other lab-developed tests		≤50 genes	Category I	5-50 gene panel	81445
		51+ genes	Category I	51+ gene panel	81455

Examples of CPT codes used in conjunction with diagnosis coding during the billing process for biomarker tests<sup>6</sup>

ICD-10-CM Codes <sup>6</sup>	CPT code category <sup>6</sup>	ICD-10-CM Codes <sup>6</sup>	CPT code category <sup>6</sup>
C34.00–C34.02	Malignant neoplasm of bronchus and lung; main bronchus	C34.30–C34.32	Malignant neoplasm of bronchus and lung; lower lobe
C34.10–C34.12	Malignant neoplasm of bronchus and lung; upper lobe	C34.80–C34.82	Malignant neoplasm of bronchus and lung; overlapping sites
C34.2	Malignant neoplasm of bronchus and lung; middle lobe	C34.90–C34.92	Malignant neoplasm of bronchus and lung; unspecified part

\*Tests listed include diagnostic tests in NSCLC that can detect KRAS mutations. The tests identified herein are examples of tests that are currently in use and are provided for educational and informational purposes only. This is not a comprehensive list, nor an endorsement to use any specific test, but rather a list of diagnostic tests that are more widely known and commonly used.

Codes identified are provided as a courtesy only and are not comprehensive or instructive. Coding and coverage policies can change without warning. The healthcare provider is solely responsible for determining coverage, coding, and reimbursement. Amgen does not guarantee coverage or reimbursement. Please check with the payer to verify codes and special billing requirements.

CPT = Current Procedural Terminology; PLA = Proprietary Laboratory Analyses; ICD-10-CM = International Classification of Diseases, 10th Revision, Clinical Modification

References: 1. Ferrera J, Sanderson ML. Accessed October 22, 2020. <https://cdn2.hubspot.net/hubfs/2758906/Navigating%20the%20Reimbursement%20Landscape%20for%20Clinical%20NGS%20Diagnostics.pdf> 2. Quest Diagnostics. Accessed December 18, 2020. <https://testdirectory.questdiagnostics.com/test/test-detail/91995/colorectal-cancer-kras-mutation-therascreen?cc=MASTER> 3. American Medical Association. Updated December 30, 2020. Accessed January 8, 2021. <https://www.ama-assn.org/system/files/2021-01/cpt-pla-codes-long.pdf> 4. ThermoFisher Scientific. Published 2020. Accessed December 17, 2020. <https://assets.thermofisher.com/TFS-Assets/LSG/brochures/oncomine-dx-target-test-brochure.pdf> 5. Foundation Medicine. Published 2020. Accessed December 16, 2020. [https://assets.ctfassets.net/w98cd481qyp0/YqqKHaqQmFeqc5ueQk48w/0a34fcd3a71d4e460c4b01cebe8ad/F1CDx\\_Technical\\_Specifications\\_072020.pdf](https://assets.ctfassets.net/w98cd481qyp0/YqqKHaqQmFeqc5ueQk48w/0a34fcd3a71d4e460c4b01cebe8ad/F1CDx_Technical_Specifications_072020.pdf) 6. Centers for Disease Control and Prevention/National Center for Health Statistics. Accessed November 18, 2020. <https://icd10cmtool.cdc.gov/?fy=FY2021&q=lung%20neoplasm>

References: 1. Data on file, Amgen; [NSCLC Payer Mix Kantar 09/2020]. 2. Foundation Medicine. Published 2018. Accessed October 22, 2020. [https://assets.ctfassets.net/w98cd481qyp0/PKWlcTAZ3RTqdZcoyGnS/545686f783e61ff7823206676bd9d72b/Foundation\\_Medicine\\_Patient\\_Billing\\_Guidelines.pdf](https://assets.ctfassets.net/w98cd481qyp0/PKWlcTAZ3RTqdZcoyGnS/545686f783e61ff7823206676bd9d72b/Foundation_Medicine_Patient_Billing_Guidelines.pdf) 3. Foundation Medicine. Accessed October 22, 2020. <https://www.foundationmedicine.com/resource/billing-and-financial-assistance> 4. 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> 5. Kim ES, et al. J Thorac Oncol. 2019;14(3):338-342.

# KRAS G12C diagnostic testing is covered for a majority of NSCLC patients<sup>1</sup>



CHECK YOUR PATIENT'S INSURANCE TO DETERMINE TEST COVERAGE



USE THE CORRECT CPT AND ICD-10 CODING



SUPPORT FOR PATIENTS, CAREGIVERS, AND PHYSICIANS

For general reimbursement questions call:

1-888-4ASSIST (1-888-427-7478) Monday to Friday, 9:00 am to 8:00 pm ET  
or visit [AmgenAssist360.com](https://www.amgen.com/AmgenAssist360)

Reference: 1. Data on file for Metastatic NSCLC Payer Mix Solution.



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# KRAS G12C Testing

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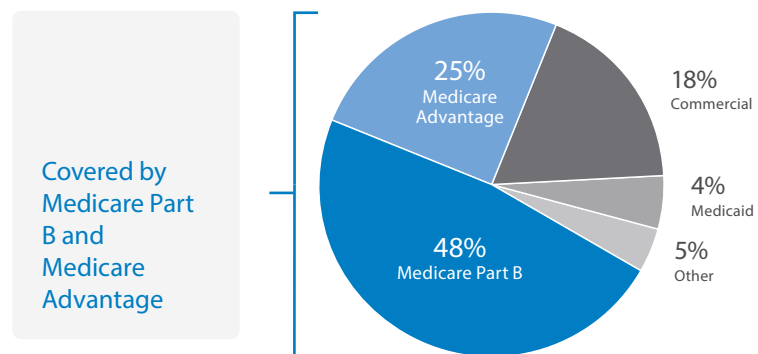
KRAS G12C is one of the most prevalent biomarkers in NSCLC, occurring in 13% of non-squamous patients<sup>1</sup>



NSCLC = non-small cell lung cancer  
Reference: 1. Data on file, Amgen; 2020.

# The majority of NSCLC patients will be covered for their biomarker tests<sup>1</sup>

## Estimated payer mix for NSCLC biomarker test<sup>1</sup>



## Other factors that can impact the insurance coverage of biomarker tests

### Sample type

- Tissue-based biomarker tests - coverage generally broader<sup>3</sup>
- Liquid-based biomarker tests - coverage more selective<sup>16</sup>

### Regulatory status<sup>10</sup>

- FDA approval is not generally required for biomarker tests to be covered by payers<sup>10</sup>

## Most patients with NSCLC have insurance coverage for KRAS G12C biomarker testing<sup>1</sup>

NGS*	
Commercially Insured Patients <sup>2-9</sup> As of January 2021, 4 out of the 5 top national commercial payers cover at least 1 NGS test	Medicare Patients <sup>10</sup> All FDA-approved tests are covered through national coverage determination

Single-Gene Tests*†	
Commercially Insured Patients <sup>2,5,11-14</sup> Single-gene KRAS testing is covered by the top 5 national commercial payers	Medicare Patients <sup>15</sup> Single-gene KRAS testing is covered through all local coverage determinations

PCR = polymerase chain reaction; NGS = next generation sequencing

\*Claim is based on membership size.<sup>17</sup>

†Payer coverage for KRAS tests may not be specific to NSCLC, and NSCLC-specific coverage is expected due to targeted therapy approval. LDT coverage varies by regional commercial payer and local Medicare contract administrator.

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# Medicare coverage for biomarker tests are set nationally or locally<sup>1</sup>

## Average patient out of pocket (OOP) for original Medicare<sup>2</sup>

Patient OOP cost will vary depending on patient's insurance. Cost estimates herein are for informational purposes only and may not actually represent what patients ultimately pay for certain tests. Further, it should not be construed as any statement, promise, or guarantee by Amgen concerning coverage and/or levels of reimbursement, payment, or charge. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently.

### National Coverage Determination (NCD)

Set nationally by CMS

Only one NCD covers FDA-approved NGS panels for patients with advanced cancer (stages III or IV) and, as of January 2021, four FDA-approved NGS panels have indications for NSCLC<sup>1,3,4</sup>

- Oncomine Dx Target Test
- Foundation One Liquid CDx
- Foundation One CDx
- Guardant360<sup>®</sup> CDx

### Local Coverage Determination (LCD)

Set locally by MACs

MACs may issue LCDs to establish coverage for NGS tests that are not covered through the NCD<sup>1</sup>

- Single-gene tests (FDA-approved or not) and non-FDA approved NGS panels, which reflect the majority of KRAS G12C tests<sup>4-10</sup>

CMS = Centers for Medicare & Medicaid Services, a federal agency that administers the Medicare program and works in partnership with state governments to administer Medicaid.

MAC = Medicare Administrative Contractors, private health insurers that manage Medicare claims for a specific region.

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## Average patient out of pocket for commercial insurance<sup>1</sup>

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## Typical steps to support coverage for biomarker tests

- 01 VERIFY BENEFITS<sup>2</sup>**  
Confirm patient's insurance coverage
- 02 MANAGE PRIOR AUTHORIZATION (PA)<sup>3</sup>**  
Submit PA form and supporting materials to insurance company (not all insurers or tests require)
- 03 ORDER TEST<sup>2</sup>**  
Provider orders biomarker test
- 04 PERFORM TEST<sup>2</sup>**  
Lab performs test
- 05 STORE TEST RESULTS<sup>5</sup>**  
Ensure test results are available to support treatment coverage

## POTENTIAL PA INFORMATION NEEDED<sup>4</sup>

- Patient diagnosis or clinical indication
- CPT code and test name
- Reason for testing/how test results will inform treatment
- Laboratory studies and results
- Prior treatments or clinical findings
- Anticipated date of test



# Sample billing and coding information for reimbursement

Many KRAS G12C biomarker tests are billed with Category I CPT codes, while some are billed with PLA codes<sup>1,2</sup>

Billing and coding errors could delay biomarker testing and impact the test reimbursement for providers and labs

Examples of CPT codes for select biomarker tests<sup>1-5</sup>

Sample type	Modality	Test name*	CPT code category	Code description	CPT codes
Tissue	PCR	Qiagen Therascreen KRAS	Category I	KRAS gene analysis	81275
	NGS	ThermoFisher Oncomine	PLA	23 gene targeted genomic sequence panel	0022U
		FoundationOne CDx	PLA	DNA gene analysis of 324 genes in solid organ tumor tissue	0037U
Liquid	NGS	Guardant360 CDx	PLA	cell-free circulating DNA analysis of 55-74 genes	0242U
Other lab-developed tests		≤50 genes	Category I	5-50 gene panel	81445
		51+ genes	Category I	51+ gene panel	81455

Examples of CPT codes used in conjunction with diagnosis coding during the billing process for biomarker tests<sup>6</sup>

ICD-10-CM Codes <sup>6</sup>	CPT code category <sup>6</sup>	ICD-10-CM Codes <sup>6</sup>	CPT code category <sup>6</sup>
C34.00–C34.02	Malignant neoplasm of bronchus and lung; main bronchus	C34.30–C34.32	Malignant neoplasm of bronchus and lung; lower lobe
C34.10–C34.12	Malignant neoplasm of bronchus and lung; upper lobe	C34.80–C34.82	Malignant neoplasm of bronchus and lung; overlapping sites
C34.2	Malignant neoplasm of bronchus and lung; middle lobe	C34.90–C34.92	Malignant neoplasm of bronchus and lung; unspecified part

\*Tests listed include diagnostic tests in NSCLC that can detect KRAS mutations. The tests identified herein are examples of tests that are currently in use and are provided for educational and informational purposes only. This is not a comprehensive list, nor an endorsement to use any specific test, but rather a list of diagnostic tests that are more widely known and commonly used.

Codes identified are provided as a courtesy only and are not comprehensive or instructive. Coding and coverage policies can change without warning. The healthcare provider is solely responsible for determining coverage, coding, and reimbursement. Amgen does not guarantee coverage or reimbursement. Please check with the payer to verify codes and special billing requirements.

CPT, Current Procedural Terminology; PLA, Proprietary Laboratory Analyses; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification

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November 18, 2020. <https://icd10cmtool.cdc.gov/?fy=FY2021&q=lung%20neoplasm>

# KRAS G12C diagnostic testing is covered for a majority of NSCLC patients<sup>1</sup>



CHECK YOUR PATIENT'S INSURANCE  
TO DETERMINE TEST COVERAGE



USE THE CORRECT CPT AND  
ICD-10 CODING



SUPPORT FOR PATIENTS, CAREGIVERS,  
AND PHYSICIANS

For general reimbursement questions call:

1-888-4ASSIST (1-888-427-7478) Monday to Friday, 9:00 am to 8:00 pm ET or visit [AmgenAssist360.com](https://AmgenAssist360.com)

Reference: 1. Data on file for Metastatic NSCLC Payer Mix Solution.



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