Molecular Pathology Reimbursement: Outcome of the 2013 Medicare Gapfilling Process

A Molecular Pathology Reimbursement Webinar Series in Partnership with Quorum Consulting

October 24, 2013

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Background and Learning Objectives

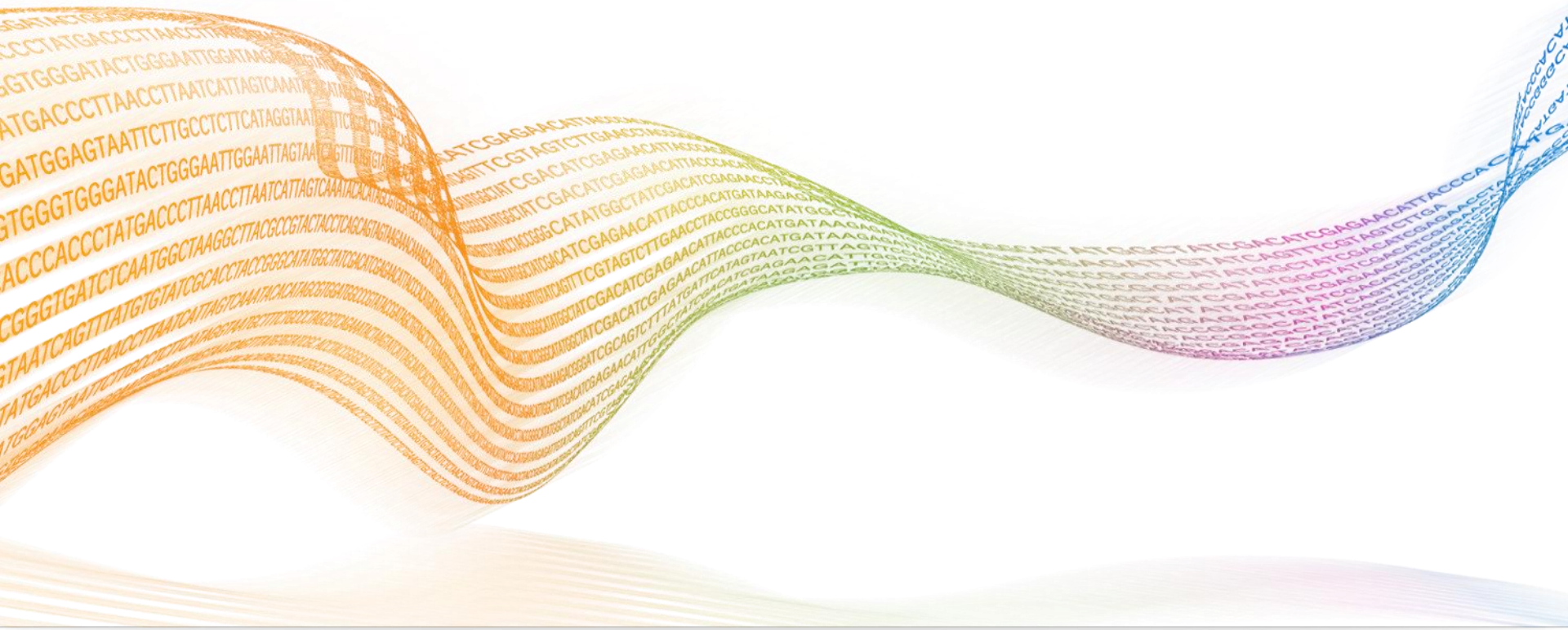
Molecular Pathology Reimbursement Webinar Series:

- This webinar summarizes the outcome of the recently concluded Medicare gapfilling process for 114 new molecular pathology (MoPath) codes that were implemented in 2013. The presentation will address the final 2013 regional rates for these codes, as well as the implications for national payment rates in 2014. We will then look ahead to additional upcoming changes in the molecular diagnostic reimbursement landscape and the potential impact on clinical laboratories.

Learning Objectives For Today's Webinar:

- Review the outcomes of the gapfilling process with an emphasis on the finalized rates that will become effective in 2014
- Understand the implications of these outcomes on clinical laboratories
- Project upcoming changes in the molecular diagnostic reimbursement landscape

Recap of the Molecular Pathology Rate Setting Process



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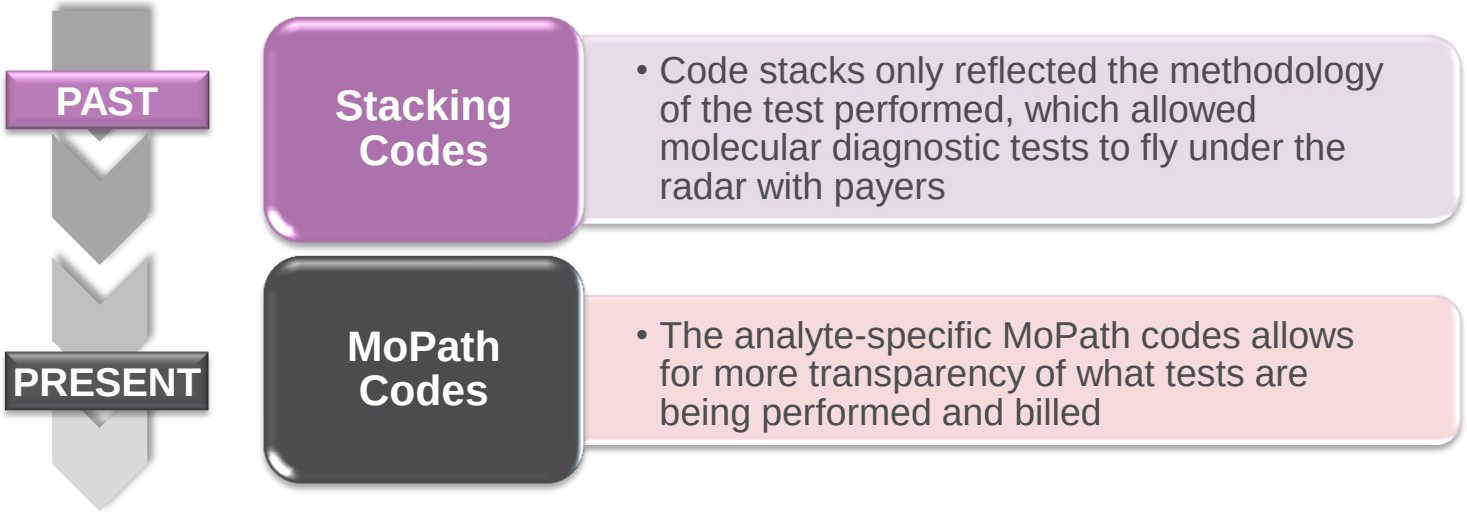
Review of the Molecular Pathology (MoPath) Codes

- In 2012, the American Medical Association (AMA) Current Procedural Terminology (CPT[1]) established the molecular pathology (MoPath) codes to replace the “stacking” CPT codes (CPT 83890-83914; 88384-88386)
- Starting January 1, 2013, the “stacking” codes were retired and laboratories are now required to bill for molecular diagnostic services using the MoPath codes



[1] CPT is a registered trademark of the American Medical Association. ©2012 American Medical Association. All rights reserved.

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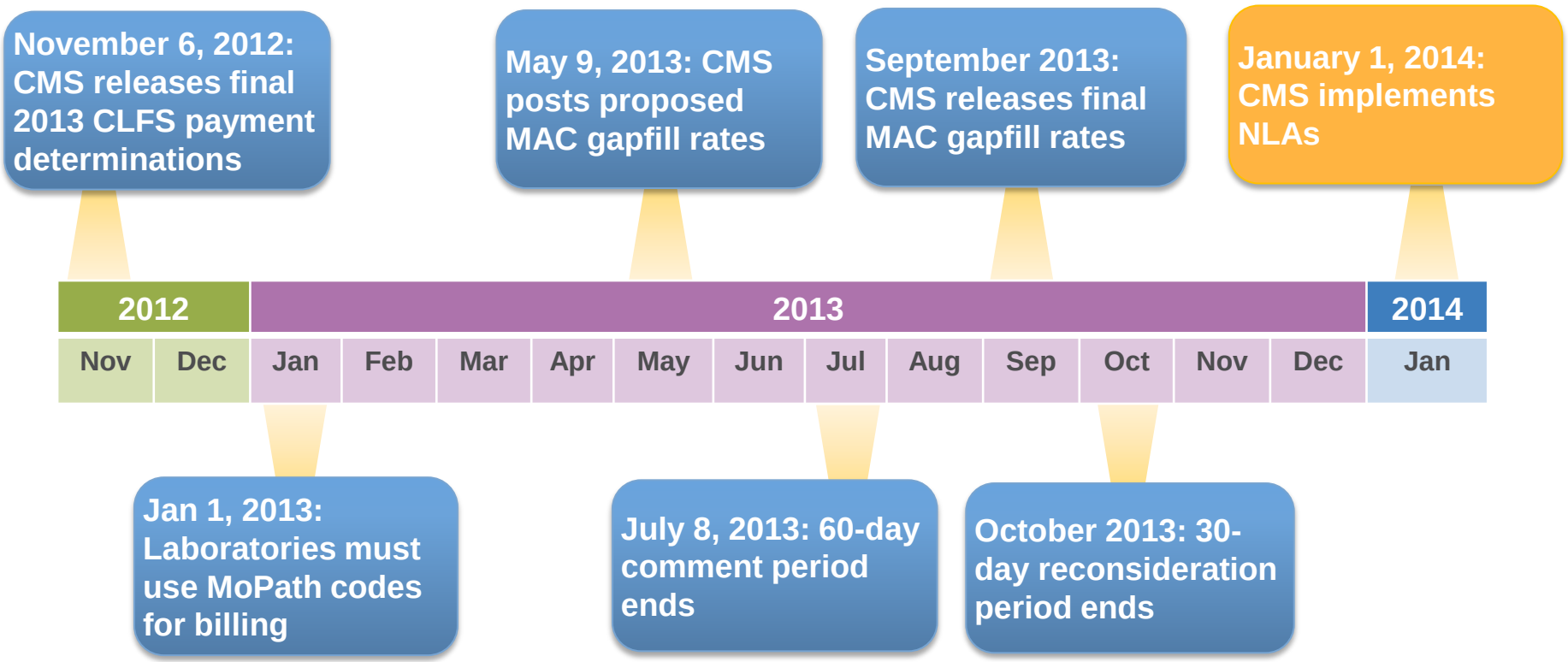
Recap of the MoPath Gapfilling Process

- In November 2012, the Centers for Medicare and Medicaid Services (CMS) determined that the Tier 1 and Tier 2 MoPath codes would be **gapfilled** under the Clinical Laboratory Fee Schedule (CLFS) for Medicare payment in 2013[1]
- This means that the local Medicare Administrative Contractors (MACs) are responsible for setting regional fee schedule amounts in 2013 for the labs in their jurisdiction
- Once these rates are finalized, a national payment rate, or National Limitation Amount (NLA), for each code is calculated as the median of the local fee schedule amounts set by the MACs and implemented in 2014

[1] Centers for Medicare and Medicaid Services. Calendar Year 2013 New and Reconsidered Clinical Laboratory Fee Schedule (CLFS) Test Codes And Final Payment Determinations. Accessed November 6, 2012, at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-CY2013-Final-Payment-Determinations-11052012.pdf

MoPath Tier 1 and Tier 2 Gapfill Timeline



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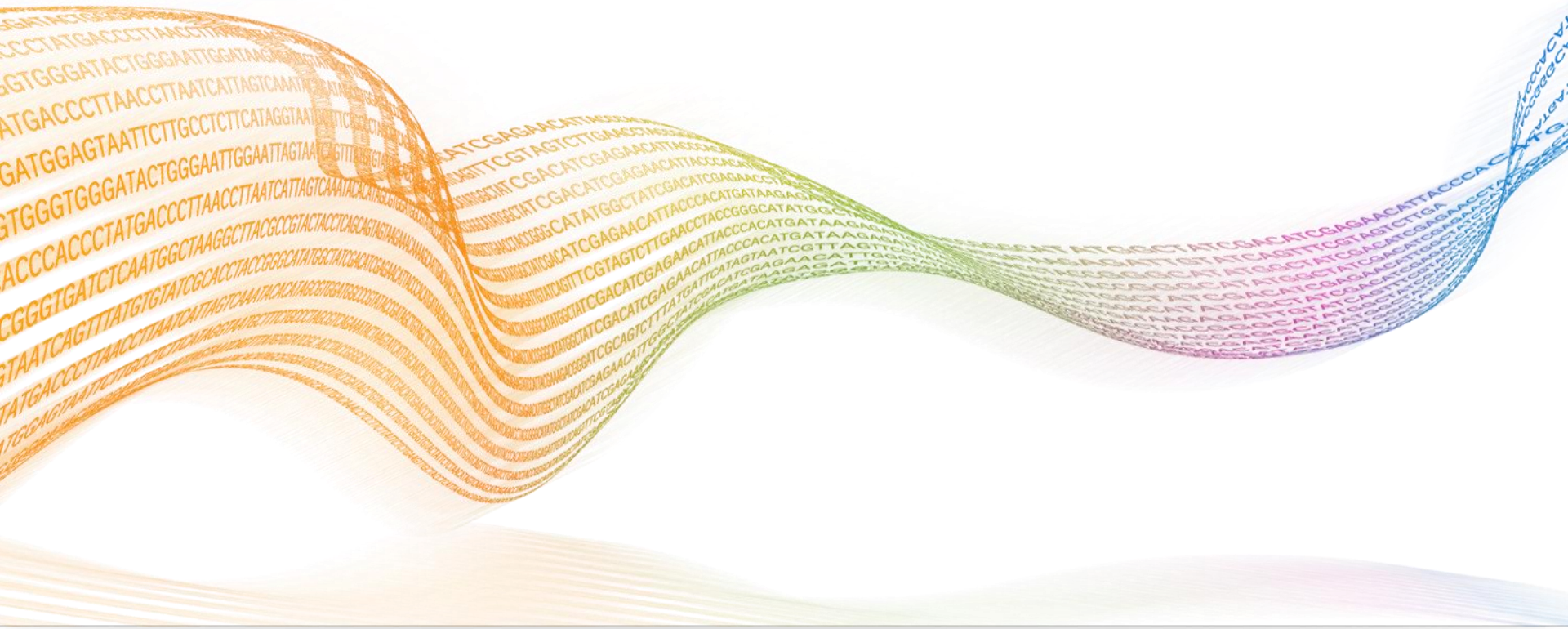
Outcome of the 2013 MoPath Gapfilling Process



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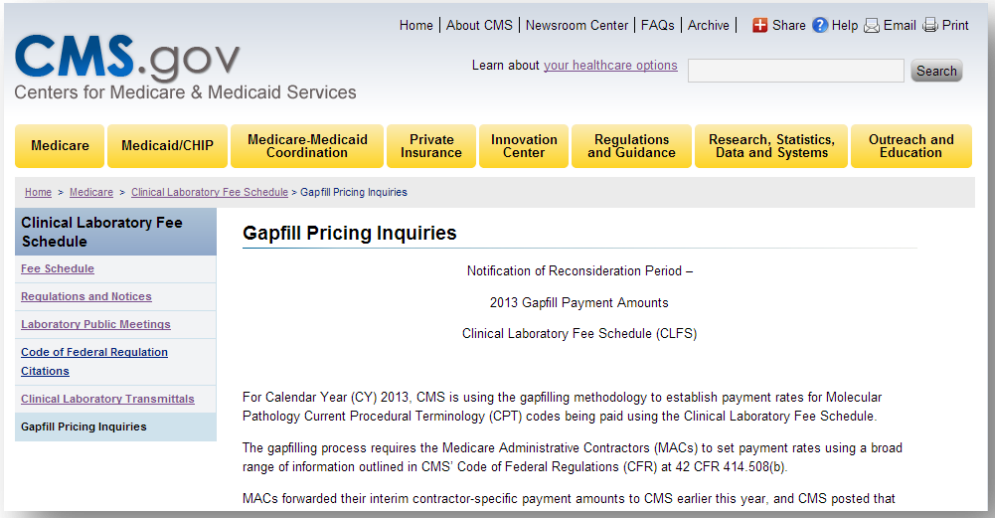
Where We Are Today

- On September 30, 2013, CMS released the finalized local MAC gapfill rates and calculated 2014 NLAs[1]
- The finalized gapfill payments do not list ALL codes but only the services currently paid by the MACs
  - Payment for these codes will likely be handled on the individual MAC level



[1] Centers for Medicare and Medicaid Services. Gapfill Pricing Inquiries. Available at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Gapfill-Pricing-Inquiries.html

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Finalized Rates for Cystic Fibrosis, Molecular Cytogenomics and Oncology Codes

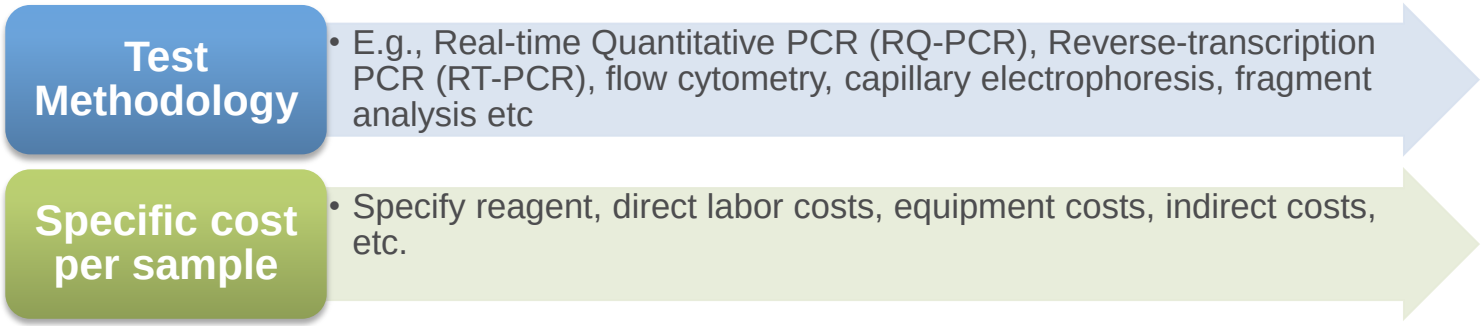
	CPT Code	2014 NLA
Cystic Fibrosis Genetic Testing	81220	$ - -
	81221	$ - -
	81222	$ - -
	81223	$ - -
	81224	$ - -
Molecular Cyto-genomics	81228	$ - -
	81229	$ - -

	CPT Code	2014 NLA
Somatic Cancer Mutations	81210	$180.60
	81235	$332.50
	81275	$198.97
	81201	$ - -
	81202	$ - -
	81203	$ - -
	81298	$ 290.01
	81299	$162.46
	81300	$162.90
	81321	$605.24
	81322	$58.84
	81323	$88.26

- These tables list the 2014 NLAs for the following codes
- Cystic fibrosis (CF) genetic testing, molecular cytogenomic testing as well as a number of somatic mutation tests are NOT listed in the revised payment file because the MACs currently do not pay for these tests

Last Steps in the 2013 Gapfill Process

- A 30 day reconsideration period is currently in place until October 30, 2013
  - This is the last opportunity for labs to reach out to CMS to dispute unsustainable rates and provide data to support appropriate rate-setting
  - CMS is requesting the following specific information from stakeholders who would like a test to be reconsidered:



- If CMS revises any NLA as a result of the reconsideration process, the revised NLA will be the upper limit on payment beginning January 1, 2014
  - Therefore, if an individual MAC establishes a price that is lower than the NLA, the local MAC may continue to pay that price in 2014

Comparing Proposed vs. Final Gapfill Rates

- There were some substantial changes between the proposed and final gapfill rates
- The table below exemplifies some of the more meaningful changes:

CPT Code	Analyte	Median Proposed Gapfill Rate	Median Final Gapfill Rate (NLA)	% Change
81210	BRAF	$97.45	$180.60	**85%**
81235	EGFR	$155.22	$332.50	**114%**
81275	KRAS	$235.00	$198.97	**-15%**

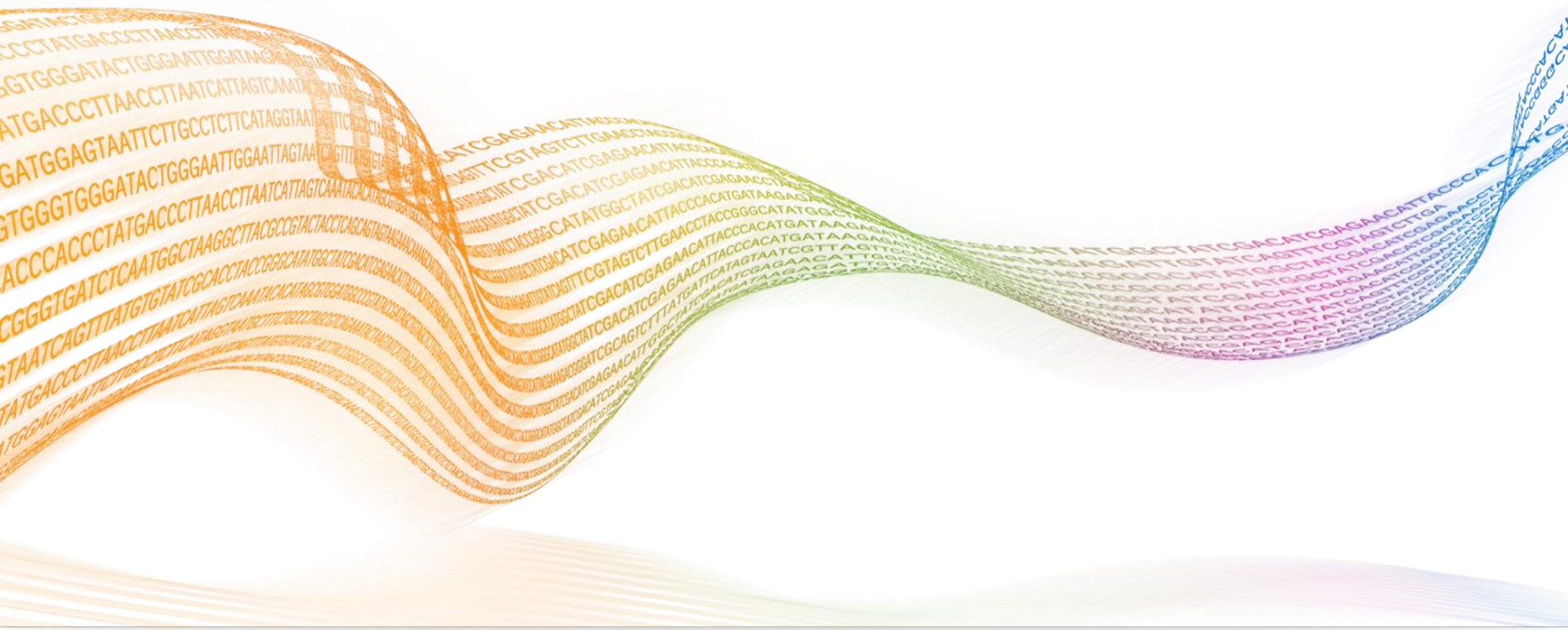
- Payment for BRAF and EGFR increased substantially while payment for KRAS decreased
- As a general trend, many of the common somatic mutation codes increased in payment. However, changes to payment rates were highly variable

What These Rates Mean for Laboratories

- Payment rates were not published for many of the codes of interest
  - CMS' rationale for not publishing final gapfill rates for certain codes was based on the fact that MACs do not currently pay for these codes. This decision had no indication on CMS' coverage stance on these codes
    - However, some MACs have issued coverage determinations that these tests are "statutorily excluded" as a Medicare benefit
    - Potentially, private payers and Medicaid may interpret the absence of these codes on the CLFS as a national non-coverage determination
  - Without Medicare payment rates as a benchmark for reimbursement for these tests, Medicaid and private payers will need to establish payment rates on their own

For codes without NLAs, laboratories should work with their local MACs to ensure coverage and engage local Medicaid programs and private payers to establish appropriate payment rates

Reviewing the Reimbursement Landscapes



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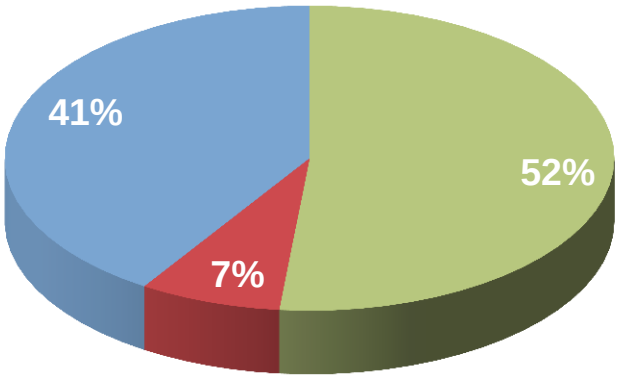
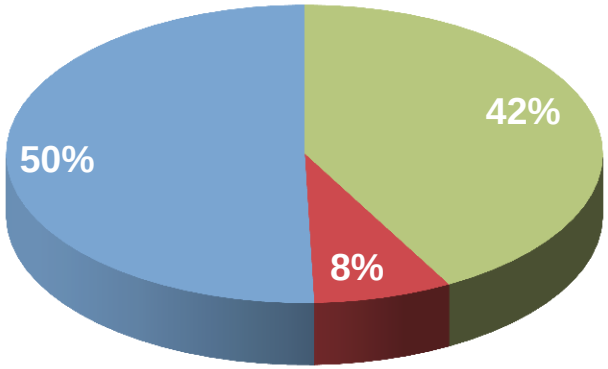
Private Payer Coverage Landscape for CF Genetic Testing

Private Payer Coverage by Number of Covered Lives*



CF Carrier Screening



CF Diagnostic Testing

Covered
Not Covered
No Policy

- In the absence of a policy for CF genetic testing, the service will generally be covered as long as medical necessity can be justified

*As of December 2012

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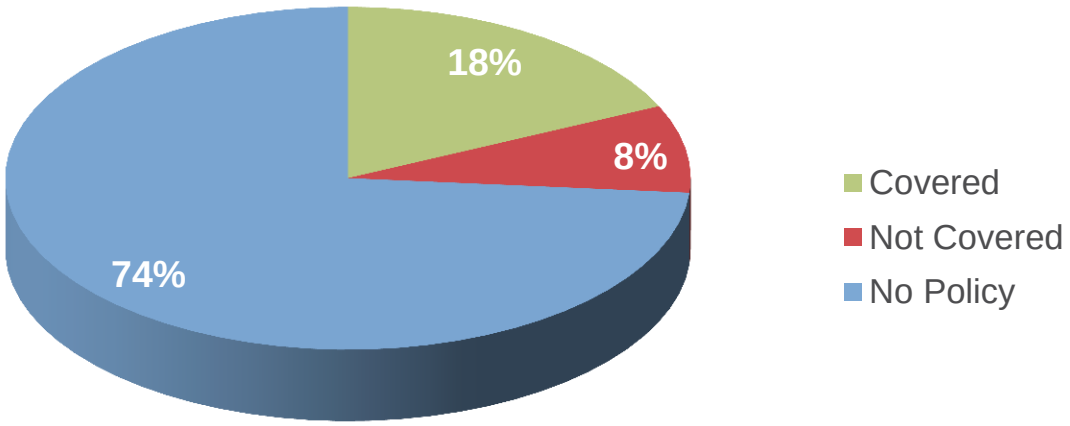
Medicaid Coverage Landscape for CF Genetic Testing

- The majority of state Medicaid agencies do not have any policies that specifically address coverage for CF genetic testing (carrier screening or diagnostic testing)
- Instead, most have general policies that cover laboratory services performed by CLIA-certified clinical labs

Medicaid Coverage by Number of Covered Lives*



*As of December 2012

Coding for Cystic Fibrosis Genetic Testing

- The following Tier 1 MoPath codes are applicable to cystic fibrosis genetic testing:

	CPT Code	Descriptor	2014 Proposed NLA*	2014 Final NLA
Cystic Fibrosis Genetic Testing	81220	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; common variants (eg, ACMG/ACOG guidelines)	$1,102.15	$ - -
	81221	Known familial variants	$105.28	$ - -
	81222	Duplication/deletion variants	$127.74	$ - -
	81223	Full gene sequence	$1,554.46	$ - -
	81224	Intron 8 poly-T analysis (eg, male infertility)	$82.58	$ - -

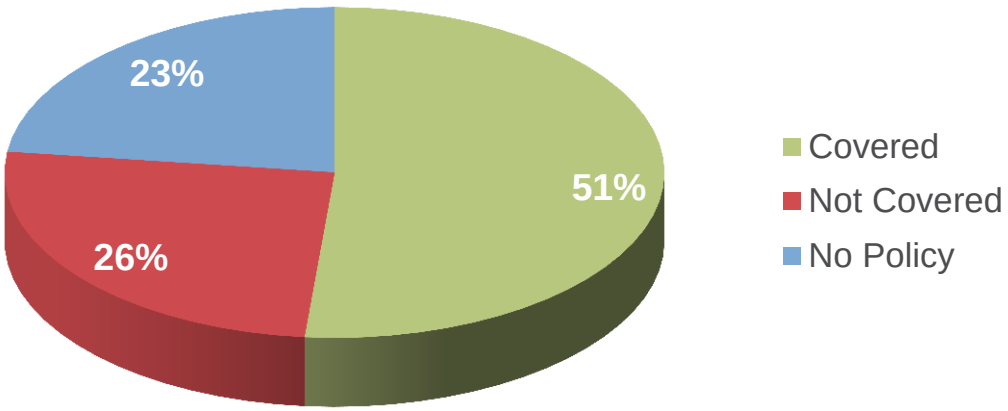
It is the responsibility of each laboratory to bill the CPT code(s) that accurately describe the CF testing services provided based on the genetic analysis performed in each case

*Although the cystic fibrosis (CF) genetic testing codes were listed in the proposed gapfill rates, they are NOT listed in the final payment file because the MACs currently do not pay for these tests

Private Payer Coverage Landscape for Molecular Cytogenomic Testing

- Postnatal molecular cytogenomic testing is currently covered for approximately 51% of private payer covered lives
- The number of positive coverage policies has been increasing in the last year, driven in part by favorable recommendations from specialty societies such as the American College of Medical Genetics (ACMG)

Private Payer Coverage by Number of Covered Lives*



*As of December 2012

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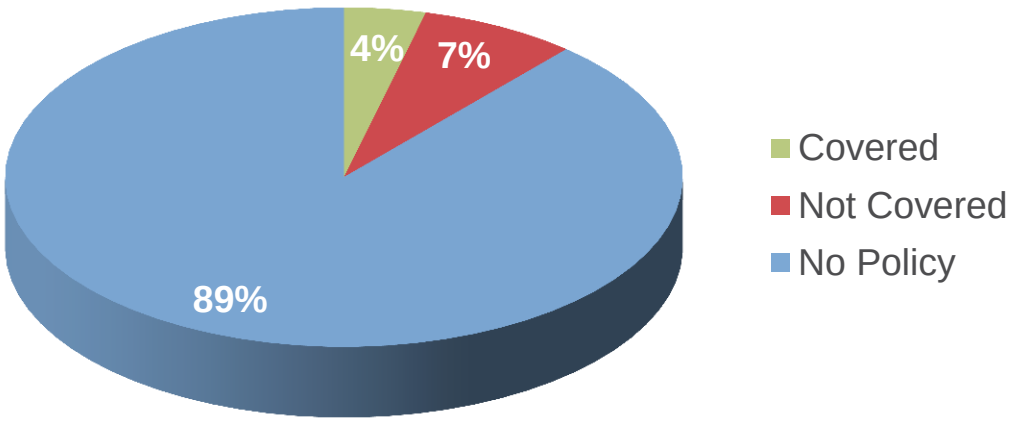
Medicaid Coverage Landscape for Molecular Cytogenomic Testing

- The majority of state Medicaid agencies do not have any policies that specifically address coverage for molecular cytogenomic testing (postnatal or prenatal)
- Instead, most have general policies that cover laboratory services performed by CLIA-certified labs

Medicaid Coverage by Number of Covered Lives*



*As of December 2012

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Coding for Molecular Cytogenomics

- The following Tier 1 MoPath codes are applicable to molecular cytogenomics:

	CPT Code	Descriptor	2014 Proposed NLA*	2014 Final NLA
Molecular Cytogenomics	81228	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (eg, Bacterial Artificial Chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)	$646.14	$ - -
	81229	Interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities	$675.56	$ - -

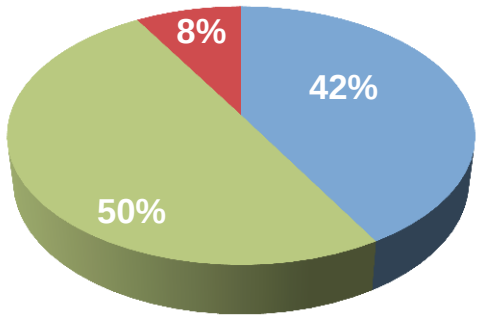
It is the responsibility of each laboratory to bill the CPT code(s) that accurately describe the molecular cytogenomic testing services provided based on the genetic analysis performed in each case

*Although the molecular cytogenomic testing codes were listed in the proposed gapfill rates, they are NOT listed in the final payment file because the MACs currently do not pay for these tests

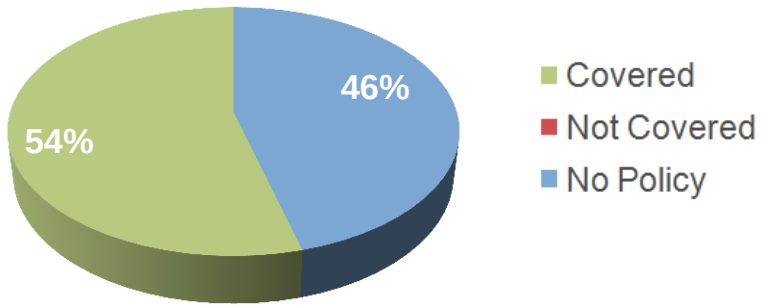
Private Payer Coverage Landscape for Oncology Genetic Testing

- Overall, the private payer environment towards genetic testing was relatively positive
- BRAF, EGFR, and KRAS genetic tests were most widely acknowledged and covered by private payers
  - BRAF tests were generally considered to be medically necessary for patients with melanoma considering treatment with vemurafenib
  - Payers responded favorably towards EGFR testing for the purpose of establishing the potential effectiveness of erlotinib (Tarceva®) in patients with non-small-cell lung cancer (NSCLC)

BRAF Private Payer Coverage by Number of Covered Lives*



EGFR Private Payer Coverage by Number of Covered Lives*



*As of June 2013

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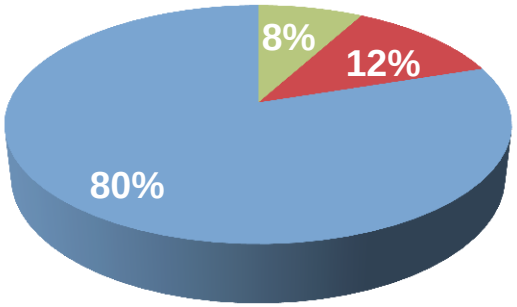
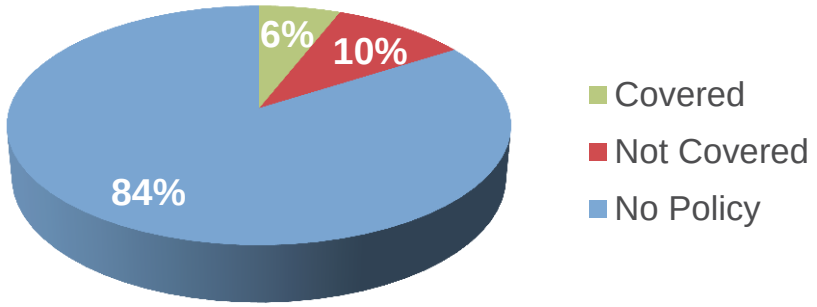
Medicaid Coverage Landscape for Oncology Genetic Testing

- The majority of state Medicaid agencies cover lab testing services in general, but do not have policies specific to oncology genetic testing
- In the absence of specific coverage guidelines/criteria, Medicaid will most likely make coverage and payment decisions on a claim-by-claim basis

BRAF Medicaid Coverage by Number of Covered Lives*



EGFR Medicaid Coverage by Number of Covered Lives*



*As of June 2013

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Coding and Payment for Oncology Genetic Testing

- The following Tier 1 MoPath codes are applicable to oncology genetic testing:

	CPT Code	Descriptor	2014 NLA
Somatic Cancer Mutations	81210	BRAF (v-raf murine sarcoma viral oncogene homolog B1) (eg, colon cancer), gene analysis, V600E variant	$180.60
	81235	EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)	$332.50
	81275	KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis, variants in codons 12 and 13	$198.97
	81201	APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; full gene sequence	$ - -
	81202	known familial variants	$ - -
	81203	duplication/deletion variants	$ - -
	81298	MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	$ 290.01
	81299	known familial variants	$162.46
	81300	duplication/deletion variants	$162.90
	81321	PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis	$605.24
	81322	known familial variants	$58.84
	81323	duplication/deletion variants	$88.26

- For genes that do not have a code that is specific to the gene interrogated, CPT Code 81479, *Unlisted molecular pathology procedure*, should be used

Common Private Payer Coverage Guidelines for Oncology Genetic Testing

- Oncology genetic testing may be covered to diagnose in individuals who meet all of the following criteria:
  - Patients have a high risk for the mutation
  - Patients need to be evaluated to predict treatment response to certain medications
- The absence of a coverage policy does not necessarily indicate non-coverage, but implies that the procedure may be covered if medical necessity can be justified

Source: Quorum Analysis of Payer Coverage Policies

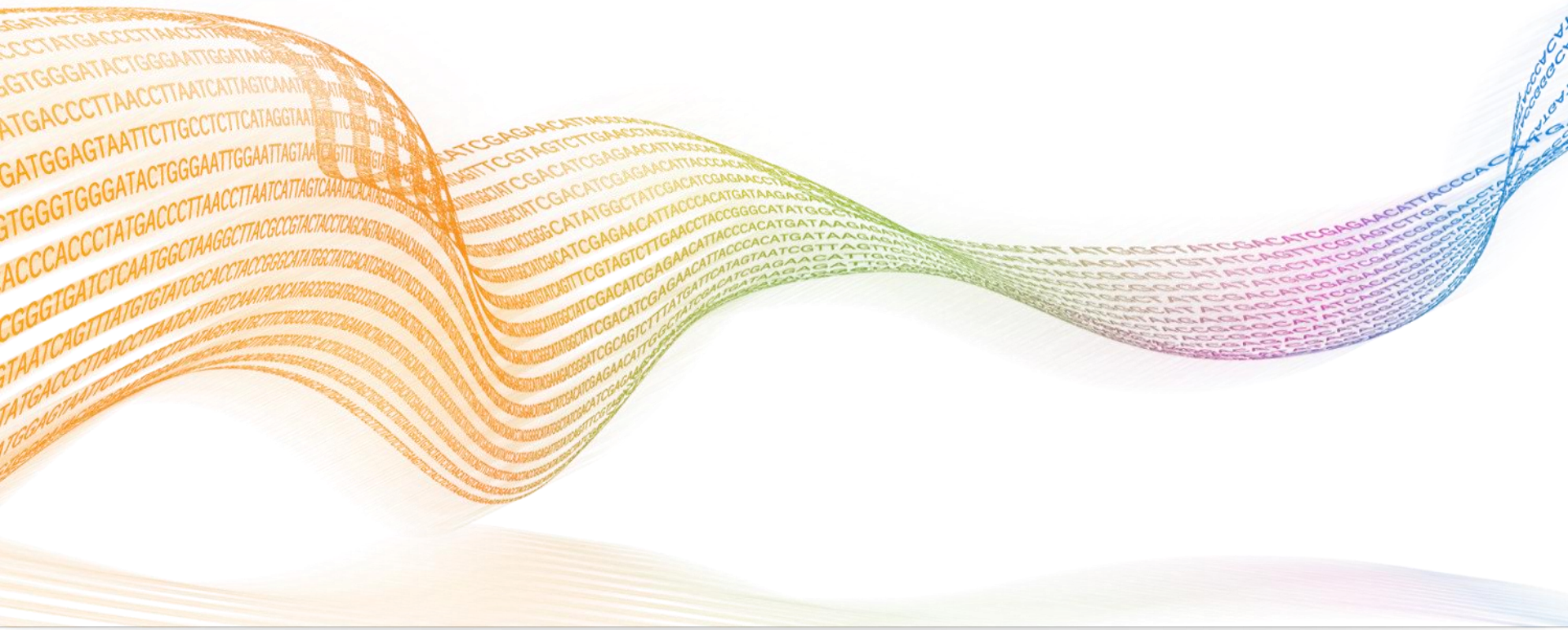
Common Coverage Criteria by Gene - Somatic Cancer

Gene	CPT Code	Gapfill Rate	Common Positive Coverage Criteria	Common Negative/Exclusion Criteria
ALK	81401	$ - -	Individuals with locally advanced or metastatic NSCLC to predict treatment response to crizotinib	All other indications not approved
BRAF	81210	$ 180.60	Tumor tissue of patients with stage IIIC or IV melanoma	Use in patients with lesser stage melanoma
EGFR	81235	$332.50	Small deletions in exon 19 and a point mutation in exon 21 (L858R) in patients with advanced non-squamous cell NSCLC	Small deletions in exon 19 and a point mutation in exon 21 (L858R) is considered experimental, investigational and unproven for patients with squamous cell NSCLC
KIT	81402; 81404	$ - -	For diagnosis of acute lymphocytic leukemia, chronic myelogenous leukemia, gastrointestinal stromal tumor (GIST), systemic mast cell disease, determining eligibility for treatment with imatinib mesylate	Not covered for melanoma, dermatofibrosarcoma protuberans, hypereosinophilic syndrome, multiple myeloma, plasma cell leukemia, breast cancer, brain cancer, monoclonal gammopathy of unknown significance, retinoblastoma
KRAS	81275	$198.97	To predict treatment response to the anti-EGFR monoclonal antibody cetuximab (Erbitux®), or panitumumab (Vectibix™) in individuals with stage IV colon, rectal, colorectal or anal adenocarcinoma prior to initiation of cetuximab or panitumumab	Routine testing; initial diagnosis
NRAS	81404	$ - -	N/A	Not covered for determination of Noonan Syndrome; Experimental and investigational
PIK3CA	81479	$ - -	N/A	Predicting non-response to anti-EGFR monoclonal antibodies cetuximab and panitumumab in the treatment of metastatic colorectal cancer

Common Coverage Criteria by Gene - Genetic Risk

Gene	CPT Code	Gapfill Rate	Common Positive Coverage Criteria	Common Negative/Exclusion Criteria
APC	81201; 81202; 81203	$ - -	Patients with greater than 20 colonic polyps; First-degree relatives of patients with FAP or AFAP and/or a known APC mutation	All other indications not approved
FGFR2	81404	$ - -	Suspected Crouzon syndrome and displays clinical features, Result will impact the treatment and definitive diagnosis remains uncertain	N/A
MAP2K1	81406	$ - -	N/A	Not covered for determination of Noonan Syndrome
MSH6	81298; 81299; 81300	$ 290.01; 162.46; 162.90	Performed after testing for MSI, IHC, MLH1 or MSH2 genes; Lynch syndrome in the family	N/A
NRAS	81404	$ - -	N/A	Not covered for determination of Noonan Syndrome; Experimental and investigational
PTEN	81321, 81322, 81323	$605.24 ; $58.84; $88.26	Family history of Cowden Syndrome or BRR	Predicting non-response to anti-EGFR monoclonal antibodies cetuximab and panitumumab in the treatment of metastatic colorectal cancer
STK11	81479	$- -	A relative with the mutation; A clinical diagnosis of PJS; Family history of PJS; mucocutaneous hyperpigmentation; 2 or more PJS polyps	N/A
TP53	81404; 81405	$- -	Family history of Li-Fraumeni syndrome	N/A

Additional Reimbursement Changes on the Horizon



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Codes for Next-Generation Sequencing (NGS) Assays are Under Development

March 2013:

The Association for Molecular Pathology (AMP) submitted an NGS coding proposal to the AMA

April 23, 2013:

The AMA held a meeting with stakeholders to discuss an NGS coding framework based on AMP's proposal

January 2015:

Likely the earliest date for implementation of any new NGS codes

Key Elements of AMP's NGS Coding Proposal[1]

- General categorization of codes from least to greatest amount of work
  - Targeted multiple gene sequencing → exome sequencing → genome sequencing
- Clinical question or condition addressed by each assay is specified (e.g., intellectual disability, inherited disorder)
- Two "partner" codes for technical and professional components of each assay
  - Potentially allows for payment of initial interpretation and reporting services as well as future re-queries

Example:

GSAX3	X-linked intellectual disability (e.g., ABCD1, ACSL4, AFF2, AGTR2, AP1S2, ARHGEF6, ARHGEF9, ARX, ATP6AP2, ATP7A, ATRX, BCOR, BRWD3, CASK, CDKL5, CUL4B,DCX,DKC1,DLG3,DMD, FANCB, FGD1, FLNA, FMR1, FTSJ1,GDI1,GK,GPC3,GRIA3,HCCS,HPRT,HSD17B10,HUWE1, IDS, IGBP1, IL1RAPL, JARID1C, KIAA2022, KLF8, L1CAM, LAMP2, MAGT1, MAOA, MBTPS2, MECP2, MED12, MID1, MTM1, NDP, NDUFA1, NHS, NLGN3, NLGN4, NSDHL, NXF5, OCRL, OFD1 ,OPHN1, OTC, PAK3, PCDH19, PDHA1, PGK1, PHF6, PHF8, PLP1, PORCN, PRPS1, PQBP1, RAB39B, RPL10, RPS6KA3, SHROOM4, SLC9A6, SLC16A2, SMC1A, SMS, SOX3, SRPX2, SYN1, SYP, TIMM8A, TM4SF2,UBE2A,UPF3B, ZDHHC9, ZDHHC15, ZNF41, ZNF81, ZNF711) genomic sequence analysis
GSAX4	Report and interpretation

[1] Association for Molecular Pathology. Proposal to address CPT coding for Genomic Sequencing Procedures. March 2013. Available at: http://www.amp.org/committees/economics/documents/AMPProposaltoAddressCodingforGenomicSequencingProcedures_FINAL.pdf

AMA's NGS Coding Development Workgroup

- The American Medical Association (AMA) CPT Editorial Panel's Molecular Pathology Work Group is currently drafting proposals on methods to report next generation sequencing panels.

- Eight subworkgroups been created to establish codes for eight applications of NGS technology:

Aortic dysfunction or dilation	**Nonsyndromic hearing loss**	**X-linked intellectual disability**	**Fetal aneuploidy**
Colon cancer panel	**Whole mitochondrial genome**	**Targeted solid organ tumor neoplasm mutations**	**Whole exome/genome**

AMA/McKesson Partnership to Crosswalk CPT Codes to Z-code™ Identifiers

- As a way to provide more clarity around the existing CPT codes, the AMA and McKesson announced a partnership to develop a reference product, CPT CodeBridge™, that maps McKesson Z-Code™ Identifiers to AMA CPT codes in the hopes to:
  - Provide the healthcare industry with a standardized way to track and identify molecular diagnostic tests
  - Allow greater specificity to the use, identification, reporting and tracking of diagnostic tests
  - Connect clinical and financial data across claims systems, electronic health records (EHRs) and other systems
  - Enable informed molecular diagnostic test selection, coverage and payment decisions
- This product will be available to providers and payers through licensing agreements with the AMA beginning in early 2014

How the AMA/McKesson Reference Product Will Work

1. Test information is submitted to the McKesson Diagnostics Exchange and assigned a Z-Code Identifier
2. The submitter can “opt-in” to share data with the AMA and participate in the mapped CPT Code process
3. Once the “opt-in” option is selected, the AMA is sent test information and related data
4. The AMA staff reviews data and makes mapping recommendations, which are reviewed by an advisory board consisting of MoPath subject matter experts
5. The AMA will update the map three times a year to keep pace with the continuous addition of new diagnostic tests

Implications of the AMA/McKesson Partnership

Increased billing transparency

- Provides further granularity to the existing MoPath codes

Potentially increased coverage scrutiny

- Payers will be able to link patient outcomes with the specific test being performed
- With the ability to link outcomes to unique tests, payers may develop test-specific coverage guidelines

Potential payment variations

- Potential for differential payments for tests that may be billed with the same CPT code (e.g., FDA approved IVD kits vs. non-FDA approved LDTs)

Questions?

For more information visit-
www.illumina.com/reimbursement