

Latest Developments in Molecular Pathology Rate Setting

A Molecular Pathology
Reimbursement Webinar in
Partnership with Quorum Consulting



Background and Learning Objectives

Molecular Pathology Reimbursement Webinar

- ▶ The Centers for Medicare and Medicaid Services (CMS) recently proposed payment rates for the new molecular pathology (MoPath) codes, with many key test areas such as molecular cytogenomics, inherited disease, and cancer having been undervalued
- ▶ Today's presentation provides an update on current MoPath rate setting developments, and reemphasizes the importance of laboratory involvement leading up to the July 8, 2013 deadline for submitting comments to CMS

Learning Objectives For Today's Webinar

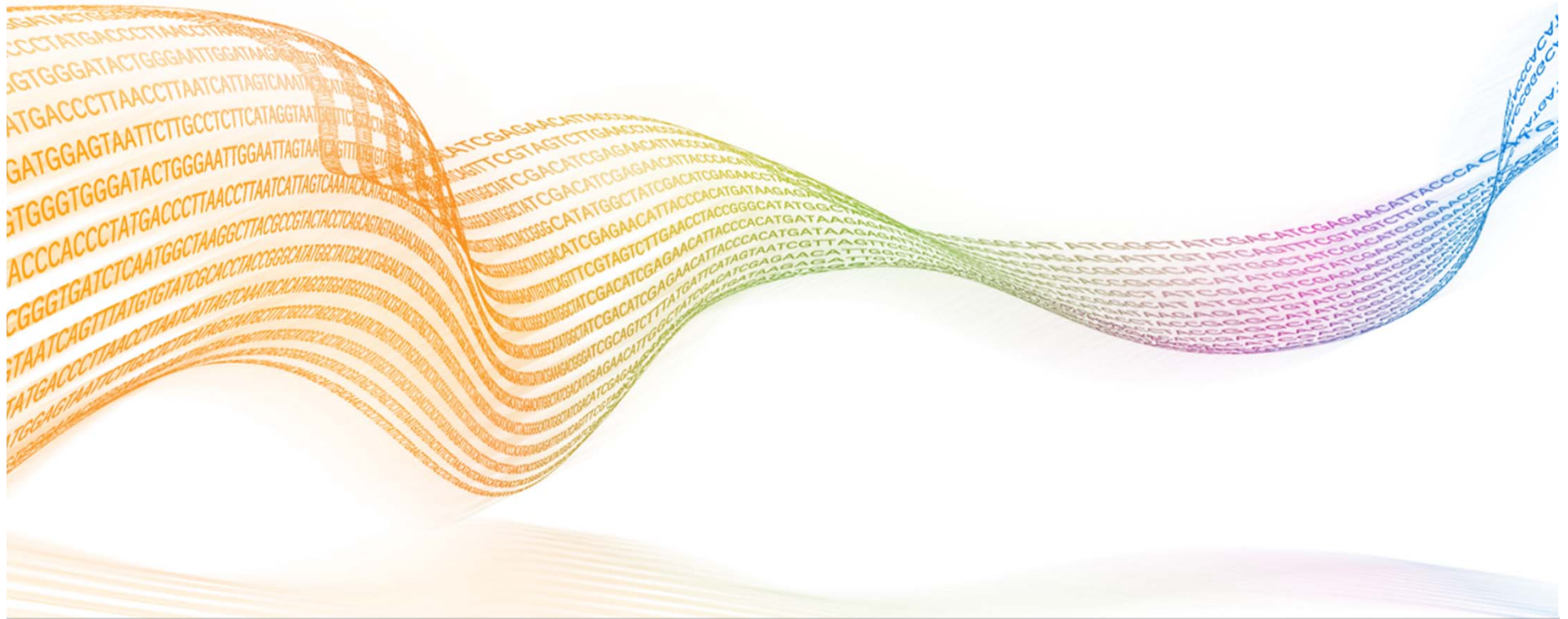
- ▶ Understand the latest developments in MoPath rate setting
- ▶ Understand how your laboratory can participate in the rate setting process **now** to ensure appropriate reimbursement for molecular diagnostic services moving forward
- ▶ Be aware of the upcoming timelines for taking action!

Immediate Action is Needed to Address the Undervaluation of Key Tests

	CPT Code	Historical Rates*	Palmetto	Novitas	First Coast	Cahaba	NGS/NHIC	Noridian/CGS	WPS
Cystic Fibrosis Genetic Testing	81220	\$1,600	\$800	\$1,344	\$1,004	\$1,200	N/A	N/A	N/A
	81221		\$94	\$94	\$117	\$123	N/A	N/A	N/A
	81222		\$129	\$460	\$126	\$123	N/A	N/A	N/A
	81223	\$1,600	\$1,554.46	\$1,554.46	\$1,674.44	\$1,200	N/A	N/A	N/A
	81224		\$82.58	\$82.58	\$82.58	\$235.00	N/A	N/A	N/A
Molecular Cyto-genomics	81228	\$1,540	\$646.14	\$646.14	\$646.14	\$123.00	N/A	N/A	N/A
	81229	\$1,540	\$675.56	\$675.56	\$675.56	\$2,900.00	N/A	N/A	N/A
Somatic Cancer Mutations	81210 (BRAF)	\$246	\$97.45	\$97.45	\$60.12	\$123.00	\$55.01	\$97.45	\$82.44
	81235 (EGFR)	\$646	\$225.00	\$225.00	\$108.19	\$123.00	\$116.25	\$225.00	\$155.22
	81275 (KRAS)	\$290	\$246.40	\$246.40	\$156.71	\$235.00	\$208.62	\$246.40	\$232.31

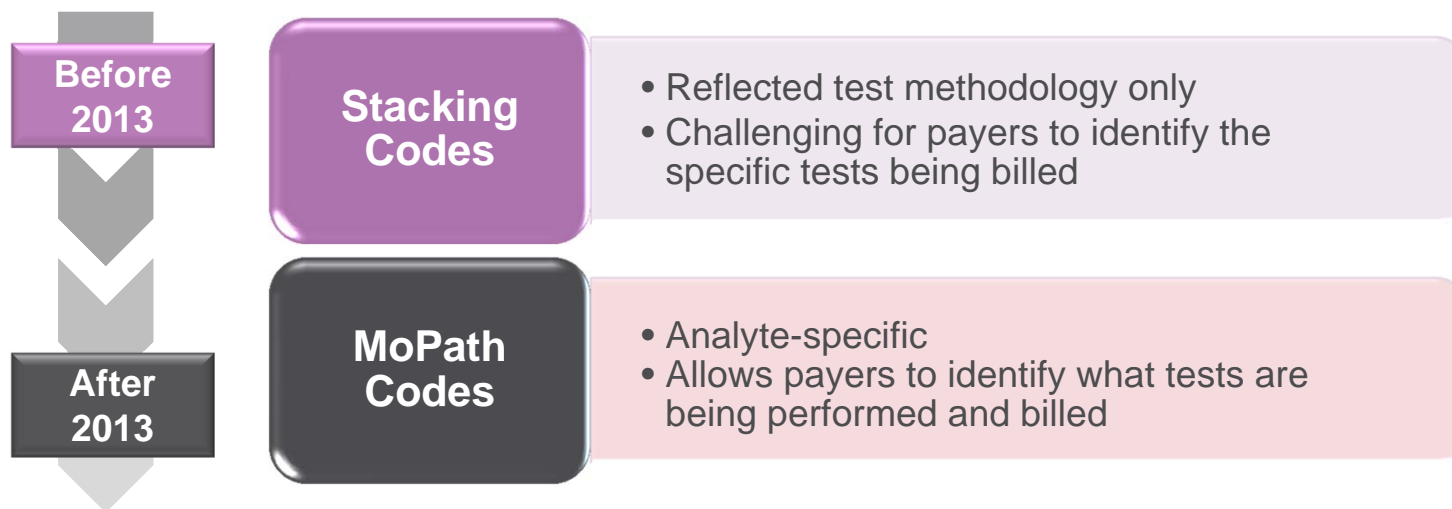
*Sources: Laboratory Economics January 2013, internal analysis, N/A = No published rate

Review of the Molecular Pathology Rate Setting Process



New Molecular Pathology (MoPath) Codes Replaced “Code Stacking” in 2013

- ▶ In 2012, the American Medical Association (AMA) Current Procedural Terminology (CPT¹) established the analyte-specific molecular pathology (MoPath) codes to replace the methodology-based “stacking” CPT codes
- ▶ Effective January 1, 2013, laboratories are required to bill for molecular diagnostic services using the new MoPath codes only



¹ CPT is a registered trademark of the American Medical Association. ©2013 American Medical Association. All rights reserved.

Examples of High-Volume MoPath Codes

	CPT Code	Descriptor
Cystic Fibrosis Genetic Testing	81220	<i>CFTR</i> (cystic fibrosis transmembrane conductance regulator) (e.g. cystic fibrosis) gene analysis; common variants (e.g. ACMG/ACOG guidelines)
	81221	Known familial variants
	81222	Duplication/deletion variants
	81223	Full gene sequence
	81224	Intron 8 poly-T analysis (e.g. male infertility)
Molecular Cytogenomics	81228	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (e.g. Bacterial Artificial Chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)
	81229	Interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities
Somatic Cancer Mutations	81210	BRAF (v-raf murine sarcoma viral oncogene homolog B1) (e.g. colon cancer), gene analysis, V600E variant
	81235	EGFR (epidermal growth factor receptor) (e.g. non-small cell lung cancer) gene analysis, common variants (e.g. exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)
	81275	KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (e.g. carcinoma) gene analysis, variants in codons 12 and 13

Overview of Medicare Rate Setting for MoPath Codes Via “Gapfilling”

2012

- In November 2012, the Centers for Medicare and Medicaid Services (CMS) announced that the MoPath codes would be **gapfilled** under the Clinical Laboratory Fee Schedule (CLFS) for Medicare payment in 2013³

2013

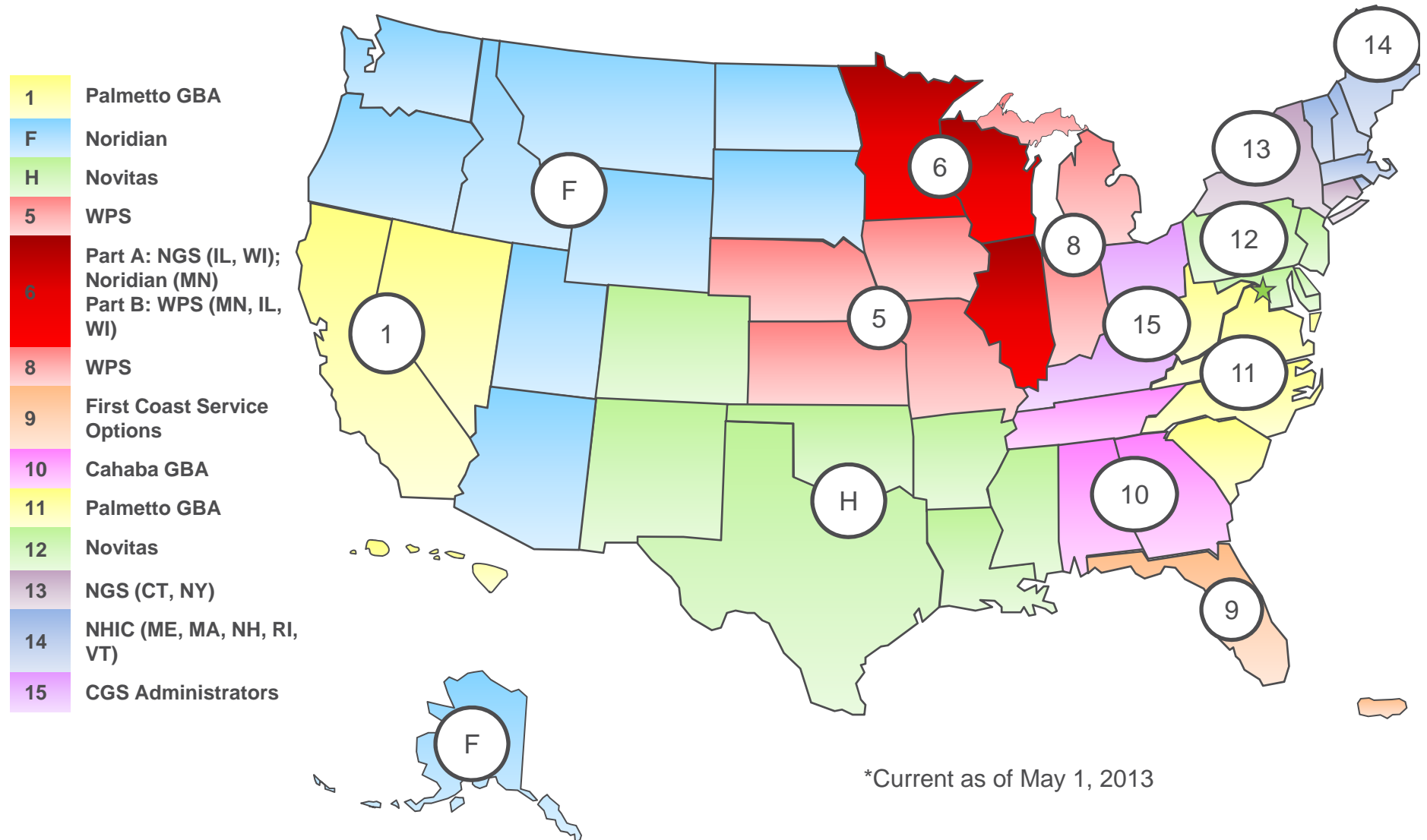
- The local Medicare Administrative Contractors (MACs) are responsible for setting regional fee schedule amounts for the laboratories in their jurisdiction

2014

- A national payment rate, or National Limitation Amount (NLA), for each code is calculated as the median of the local MAC fee schedule amounts finalized in 2013

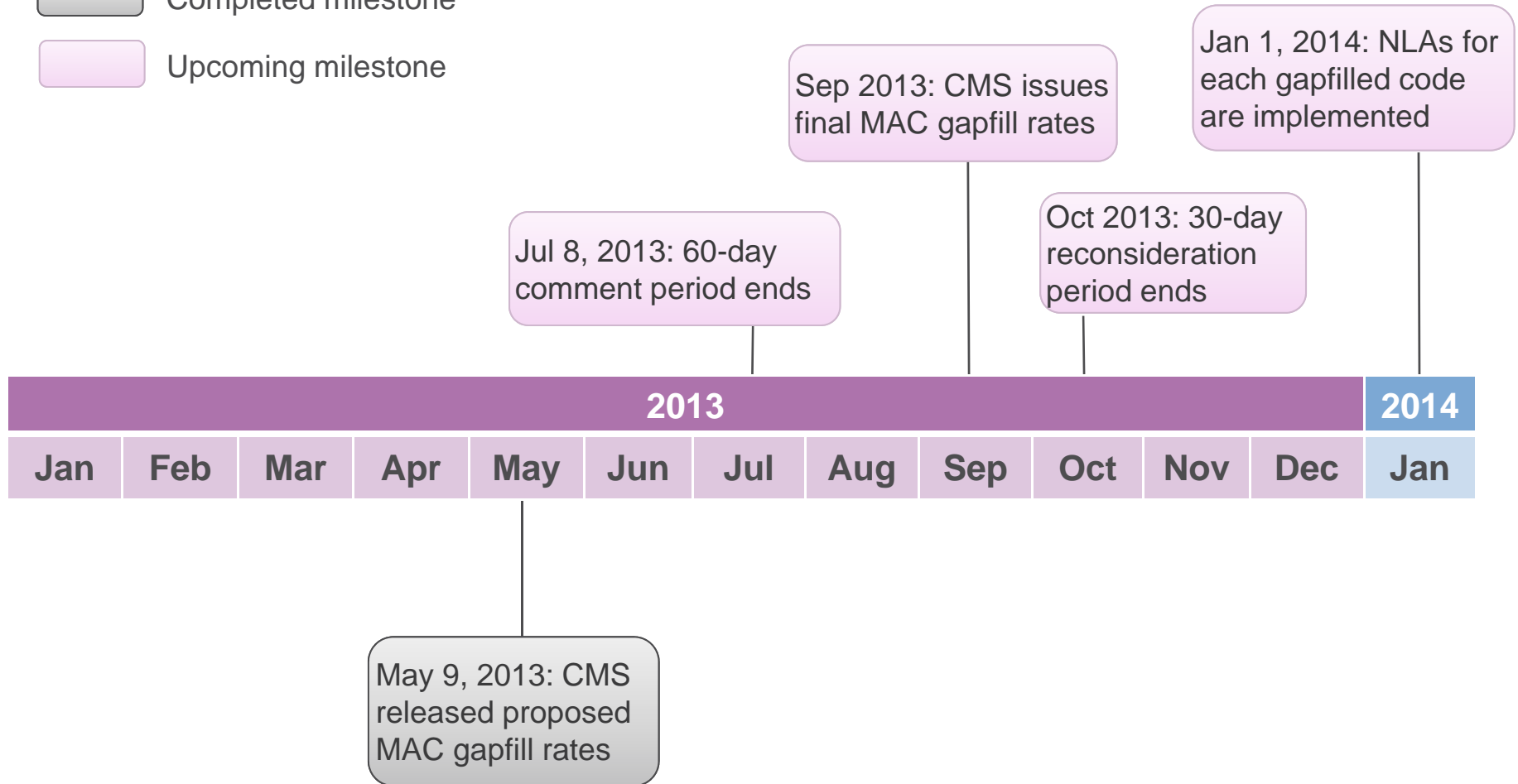
³ Centers for Medicare and Medicaid Services. Calendar Year 2013 New and Reconsidered Clinical Laboratory Fee Schedule (CLFS) Test Codes And Final Payment Determinations. Accessed November 6, 2012, at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-CY2013-Final-Payment-Determinations-11052012.pdf>

Medicare Administrative Contractor (MAC) Map*



2013 Medicare Gapfilling Timelines

- Completed milestone
- Upcoming milestone

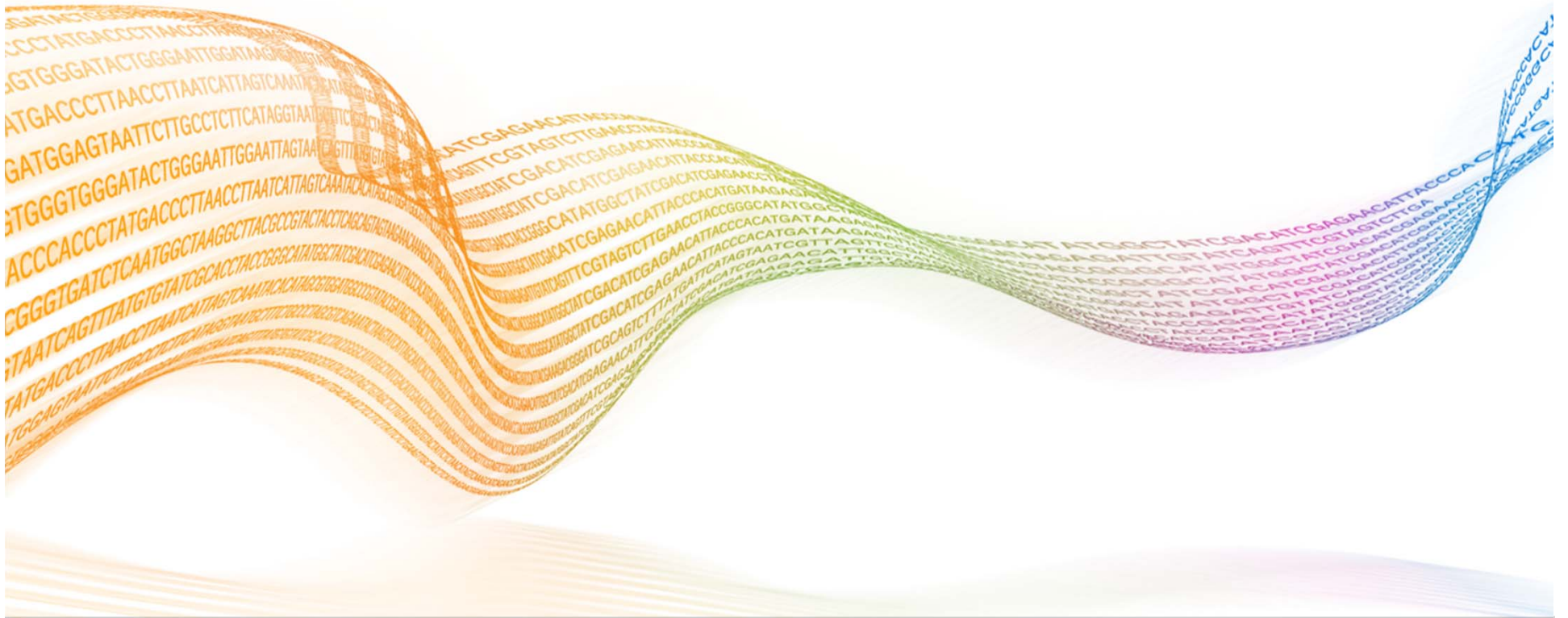


Medicare Rate Setting Will Influence Other Payers As Well

- ▶ Medicaid and private payers employ a variety of methodologies to determine payment rates for laboratory testing services, including molecular diagnostics
- ▶ They often use Medicare rates as a point of reference in setting their own
 - E.g., payment made at X% of the Medicare rate for a given CPT code
 - State Medicaid agencies generally set rates *not to exceed* the corresponding Medicare fee schedule amount

Even if Medicare is not a significant payer for your laboratory, what happens in the Medicare rate setting process will still affect you.

Recent Developments in the Medicare Gapfilling Process



Where We Are Today

- ▶ On May 9, 2013, CMS released the proposed gapfill rates for all MACs, as well as certain MACs' rationale for specific tests⁴
- ▶ **CMS will accept comments on these proposed rates until July 8, 2013**
 - Feedback collected by CMS will be shared with the MACs as well

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Clinical Laboratory Fee Schedule

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- Regulations and Notices
- Laboratory Public Meetings
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- Gapfill Pricing Inquiries

Gapfill Pricing Inquiries

Notification of Comment Period –
2013 Gapfill Payment Amounts
Clinical Laboratory Fee Schedule (CLFS)

For Calendar Year (CY) 2013, CMS determined it was most appropriate to use the gapfilling methodology to establish payment rates for the approximately 114 new Molecular Pathology Current Procedural Terminology (CPT) codes as well as 1 additional test code that fell into another category.

The gapfilling process requires the Medicare Administrative Contractors (MACs) to set payment rates using a broad range of information outlined in CMS' Code of Federal Regulations (CFR) at 42 CFR 414.508(b).

As that process was completed, the MACs forwarded their interim carrier-specific payment amounts to CMS, and CMS is now required to post that information on its web site. The information is available at <http://www.cms.hhs.gov/ClinicalLabFeeSched> in two files – one file contains the Medicare payment amounts by State

⁴ <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Gapfill-Pricing-Inquiries.html>

Sampling of Proposed MAC Payment Rates

	CPT Code	Historical Rates*	Palmetto	Novitas	First Coast	Cahaba	NGS/NHIC	Noridian/CGS	WPS
Cystic Fibrosis Genetic Testing	81220	\$1,600	\$800	\$1,344	\$1,004	\$1,200	N/A	N/A	N/A
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*Sources: Laboratory Economics January 2013, internal analysis, N/A = No published rate

Analyzing the Proposed MAC Gapfill Rates

Out of all 9 MACs, only Cahaba has issued payment rates for all 114 codes

- Palmetto and First Coast Service Options (FCSO) have both developed payment rates for the vast majority of codes as well

Most MACs collaborated or followed Palmetto's lead in rate setting for numerous codes

- Noridian, CGS, Novitas, and WPS used Palmetto's payment rates for many or nearly all of the MoPath codes
- With a few exceptions, NGS and NHIC essentially have the same fee schedule

There is no clear rationale for how each MAC arrived at their proposed payment rates

- The lack of clear and understandable methodologies is troubling
- Most seem arbitrary – e.g., Cahaba assigned most codes to the same rate of \$123

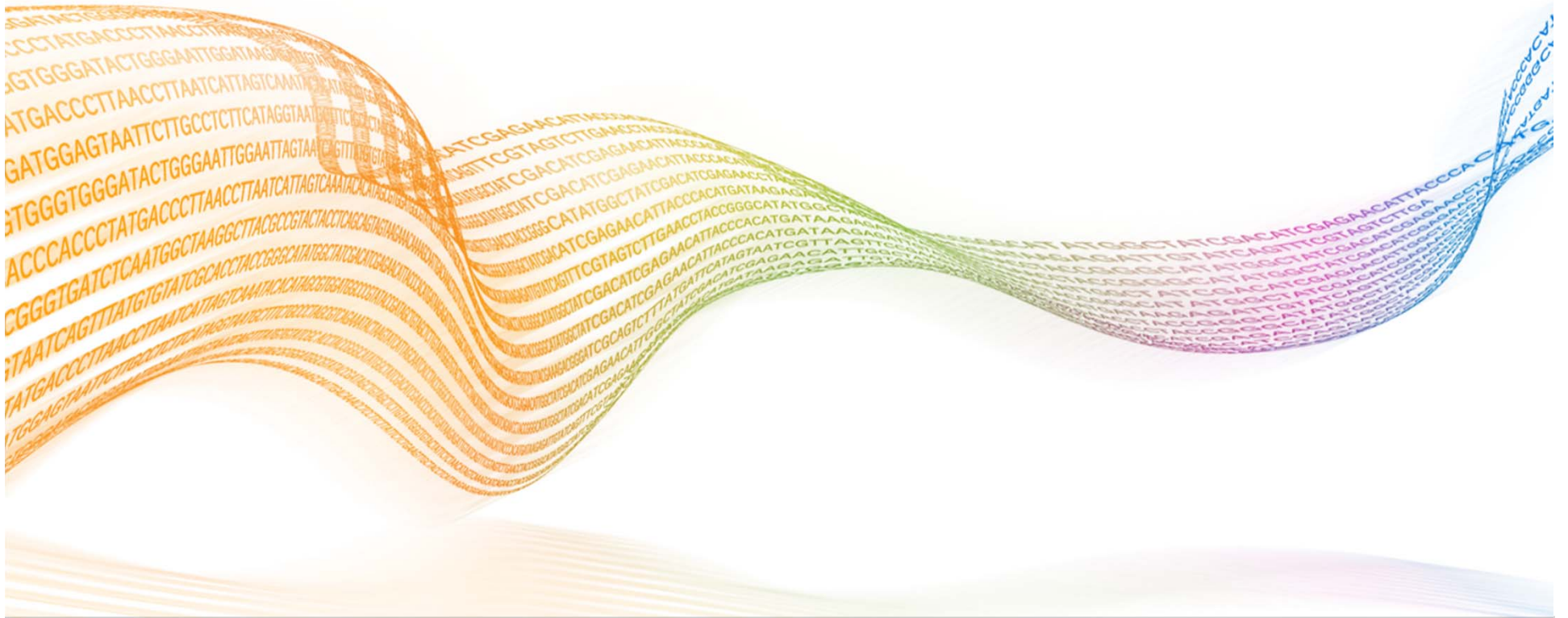
Potential 2014 National Medicare Payment Rates

	CPT Code	Potential 2014 NLA
Cystic Fibrosis Genetic Testing	81220	\$1,102.15
	81221	\$105.28
	81222	\$127.74
	81223	\$1,554.46
	81224	\$82.58
Molecular Cyto-genomics	81228	\$646.14
	81229	\$675.56
Somatic Cancer Mutations	81210 (BRAF)	\$97.45
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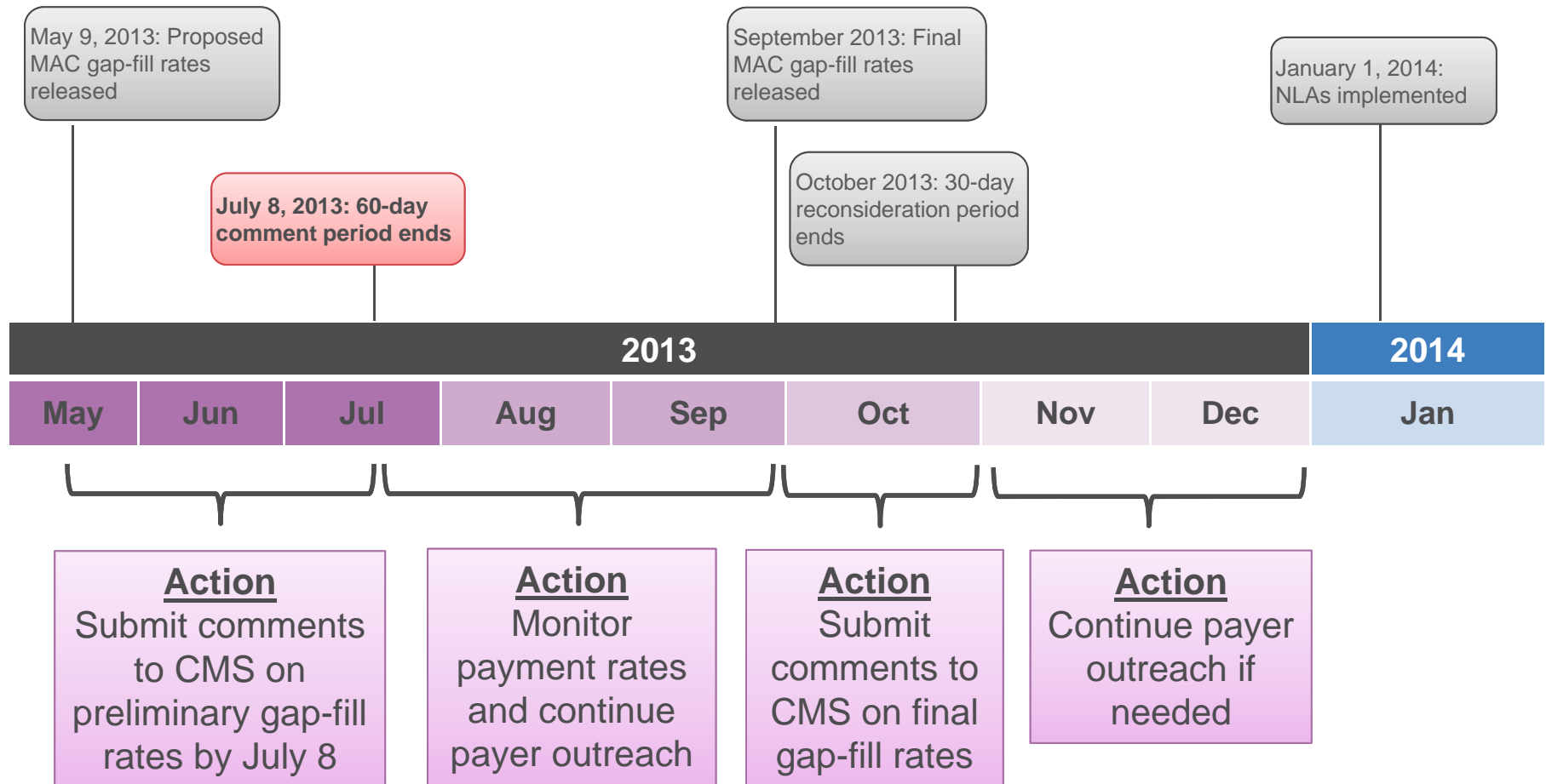
- ▶ If the proposed MAC gapfill rates were to be finalized, the table to the left identifies the National Limitation Amount (NLA) for each code in 2014
 - Remember: The NLA for each code will be determined as the median of the local MAC gap-fill rates finalized in 2013

Would these rates provide sustainable reimbursement for your laboratory?

Timelines and Resources for Effective Laboratory Advocacy



Aligning Advocacy Efforts with Gapfilling Milestones

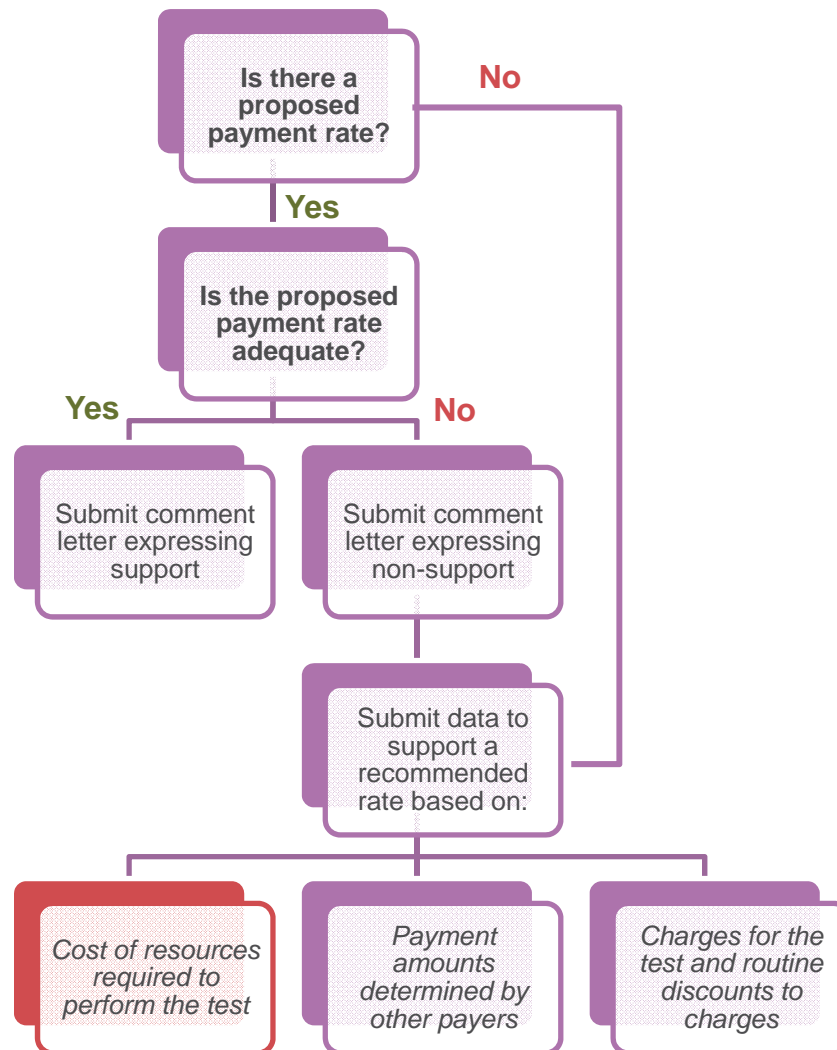


Laboratories are Strongly Encouraged to Comment on the Proposed MAC Gapfill Rates

- ▶ The current 60-day comment period is the most critical window for Medicare advocacy efforts
- ▶ **Comments need to be submitted to MoPathGapfillInquiries@cms.hhs.gov by July 8, 2013**
- ▶ Commenters should provide cost, test methodology, and any other information to support evaluation and revision of pricing for particular codes
- ▶ Laboratories are strongly encouraged to submit comments to both CMS and their local MACs

***Reimbursement for molecular diagnostics is in jeopardy.
Take action NOW to effect positive change.***

Rate Setting Advocacy Formula: How To Respond to Proposed MoPath Payment Rates



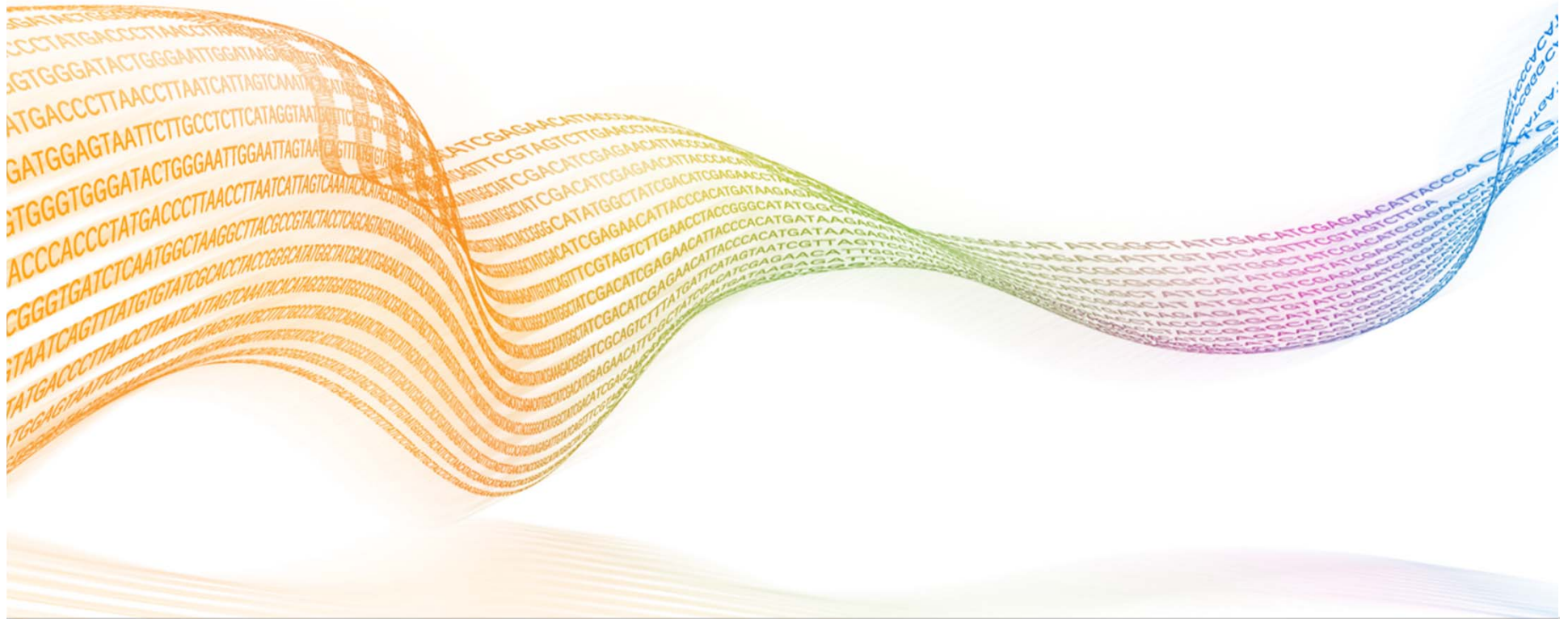
- ▶ Cost of resources required for each test should include:
 - Capital equipment costs
 - Disposable equipment costs
 - Staff laboratory costs (for both technical test performance and interpretation of results)
 - Overhead costs (e.g., utilities, rent, admin)
 - R&D costs

Need Help Getting Started? Visit the Illumina Website to Download Rate Setting Advocacy Resources

- ▶ The following resources are currently available to support your payer advocacy efforts:
 - Action plan for your rate setting advocacy activities
 - Advocacy letter template
 - Cost analysis tool to evaluate your laboratory's comprehensive costs of testing
 - Information on specialty society advocacy initiatives

Visit our website at
<http://www.illumina.com/reimbursement>
to download these resources and more

New Codes for Next-Generation Sequencing (NGS) Technology



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

January 2015:

Likely the earliest date for implementation of any new NGS codes

April 23, 2013:

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

Key Elements of AMP's NGS Coding Proposal¹

- ▶ 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/AMPPProposaltoAddressCodingforGenomicSequencingProcedures_FINAL.pdf

Questions?

