Overview of the AMA Molecular Pathology CPT codes and Reimbursement

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UF | Precision Medicine Conference

Clinical Laboratory Testing and Reimbursement in Pharmacogenetics

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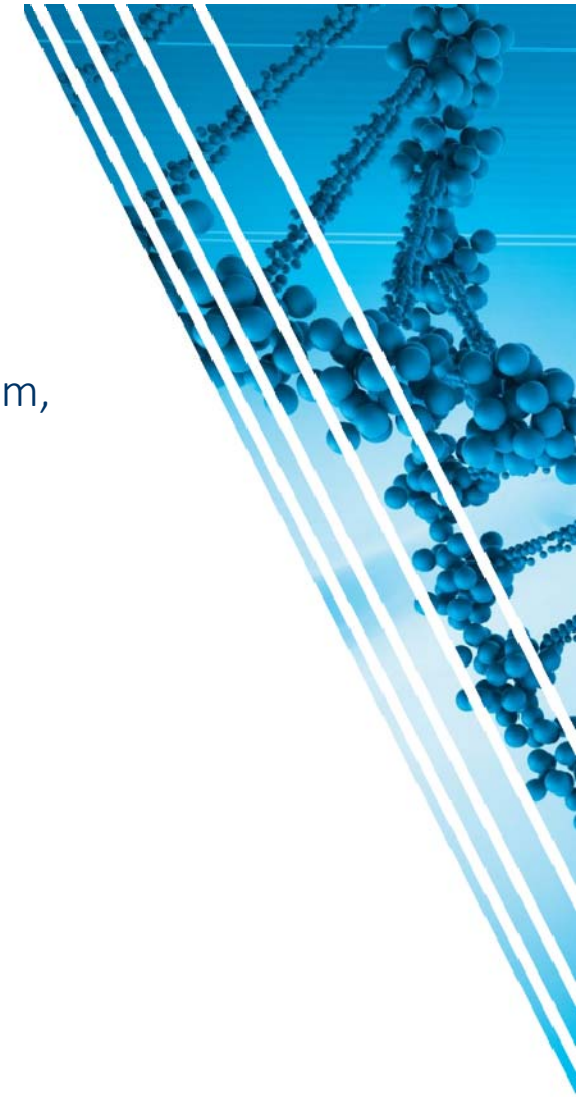
Disclosure

- I declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

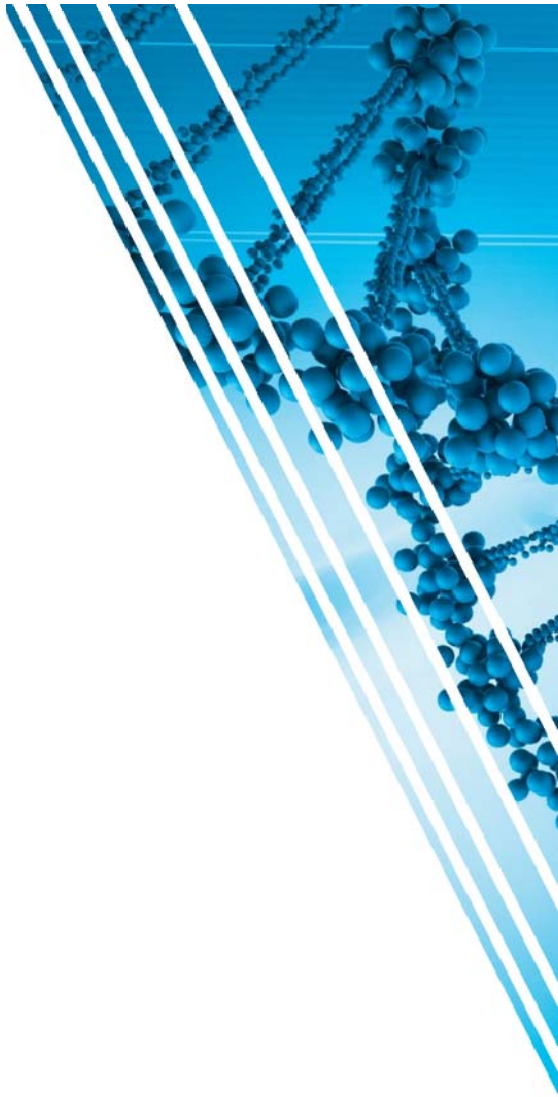
- Note: I am a member of AMA Molecular Pathology Workgroup, AMA Propriety Laboratory Assay Technical Advisory Group, and Center for Medicare and Medicaid Services, Advisory Panel Member on Clinical Diagnostic Laboratory Tests (all are voluntary positions)

- The University of Florida College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.



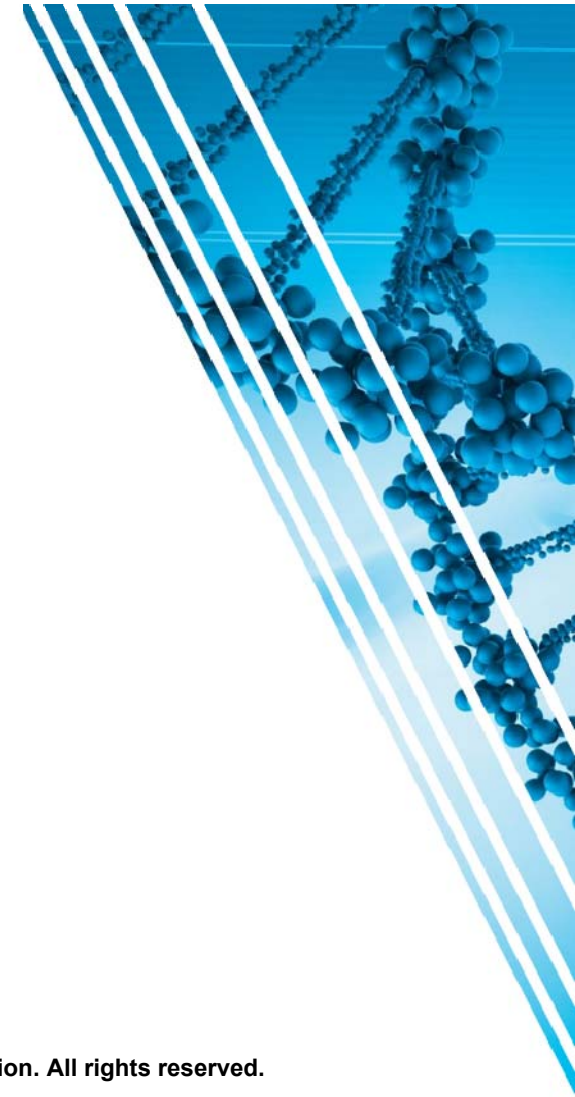
Objectives

- Describe laboratory testing and reimbursement models for pharmacogenetic testing.
- Compare and contrast various strategies and methods for pharmacogenetic testing and reimbursement in clinical practice
- Summarize reimbursement challenges in precision medicine and strategies for overcoming these challenges.
- Determine appropriate use of CPT coding for pharmacogenetic testing



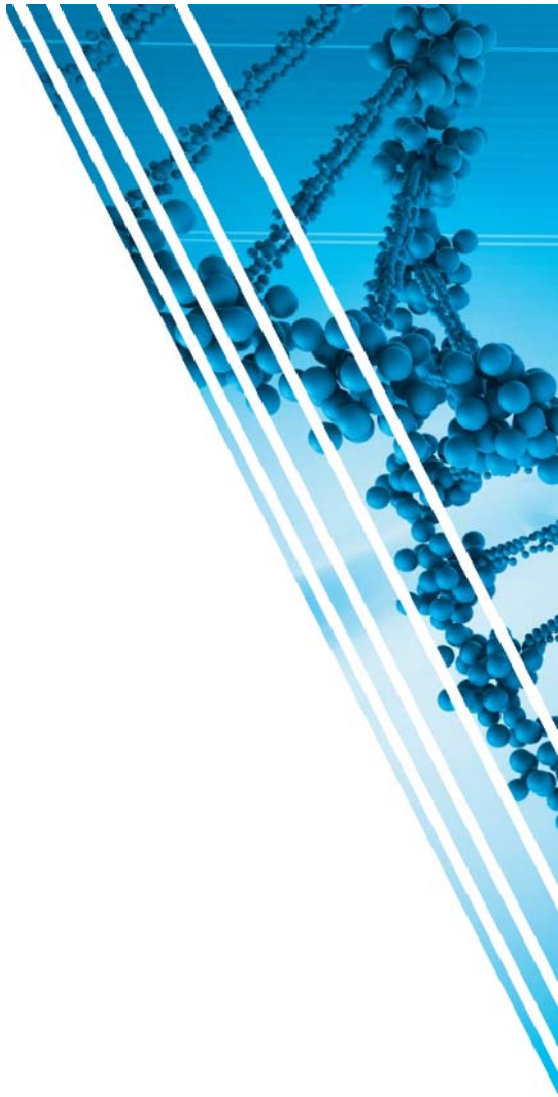
Reimbursement and CPT codes

- CPT code ≠ reimbursement
- List of services

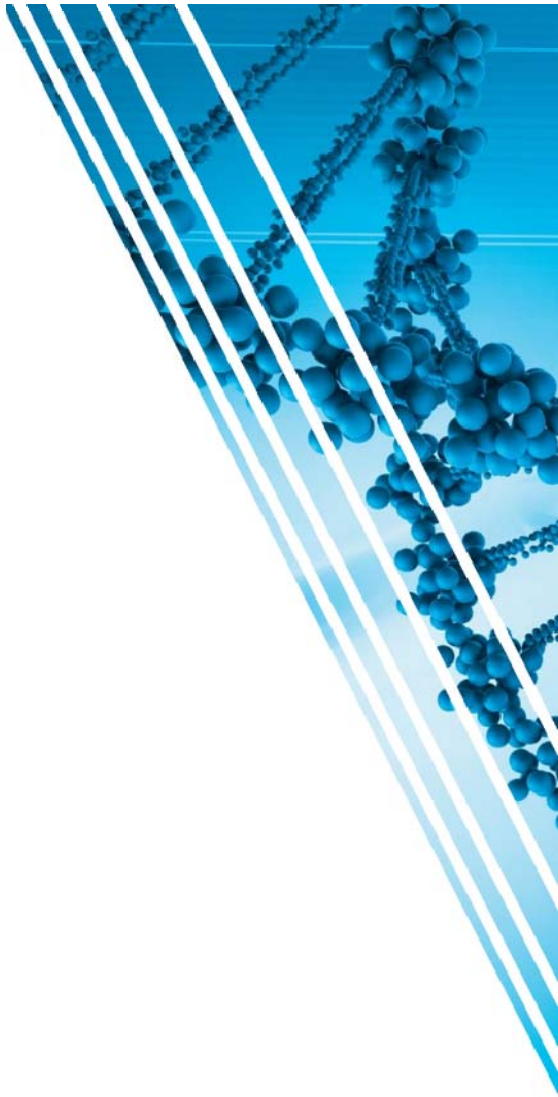


On a scale of 1 to 5, how confident do you feel in your knowledge of pathology CPT codes and reimbursement?

- 1
- 2
- 3
- 4
- 5

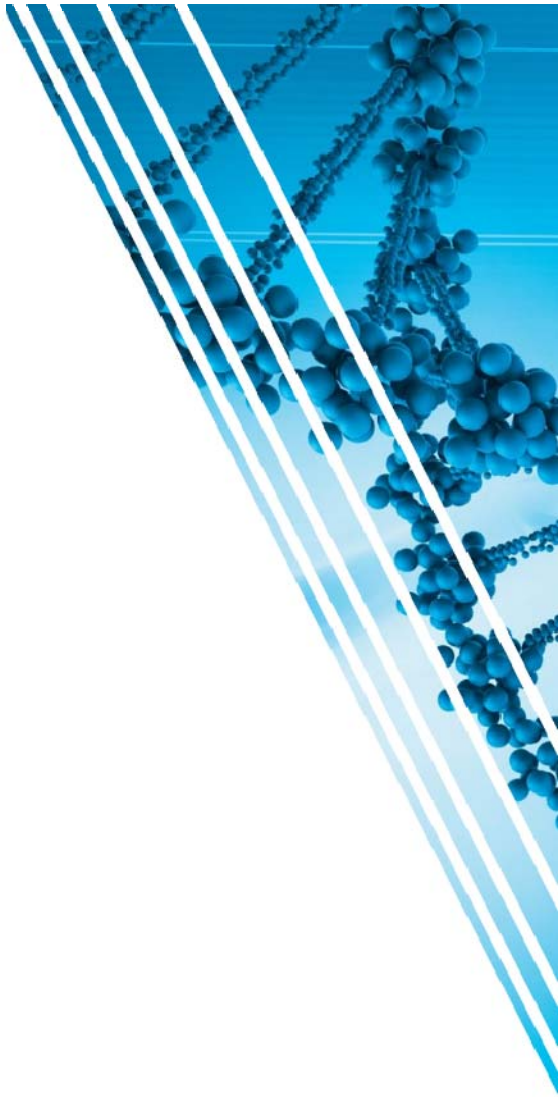


CPT CODES



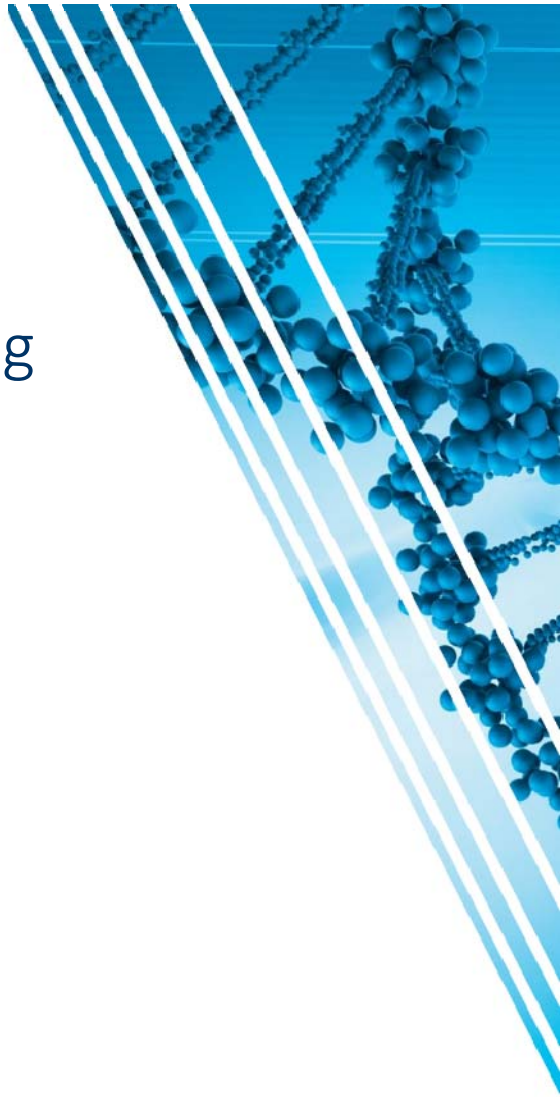
Before January 1, 2013

- Used Molecular “stacking” CPT codes to get reimbursed
  - Each step of test utilized a different CPT code to create a “stack”



Why the new Molpath CPT codes?

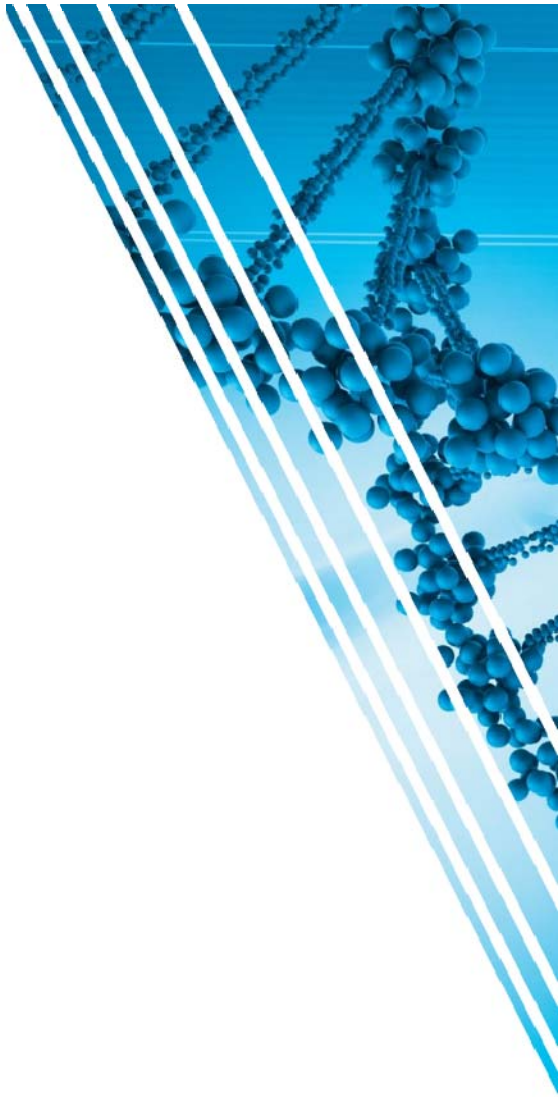
- Payers wanted to know for what they were paying
- Needed clear and granular system



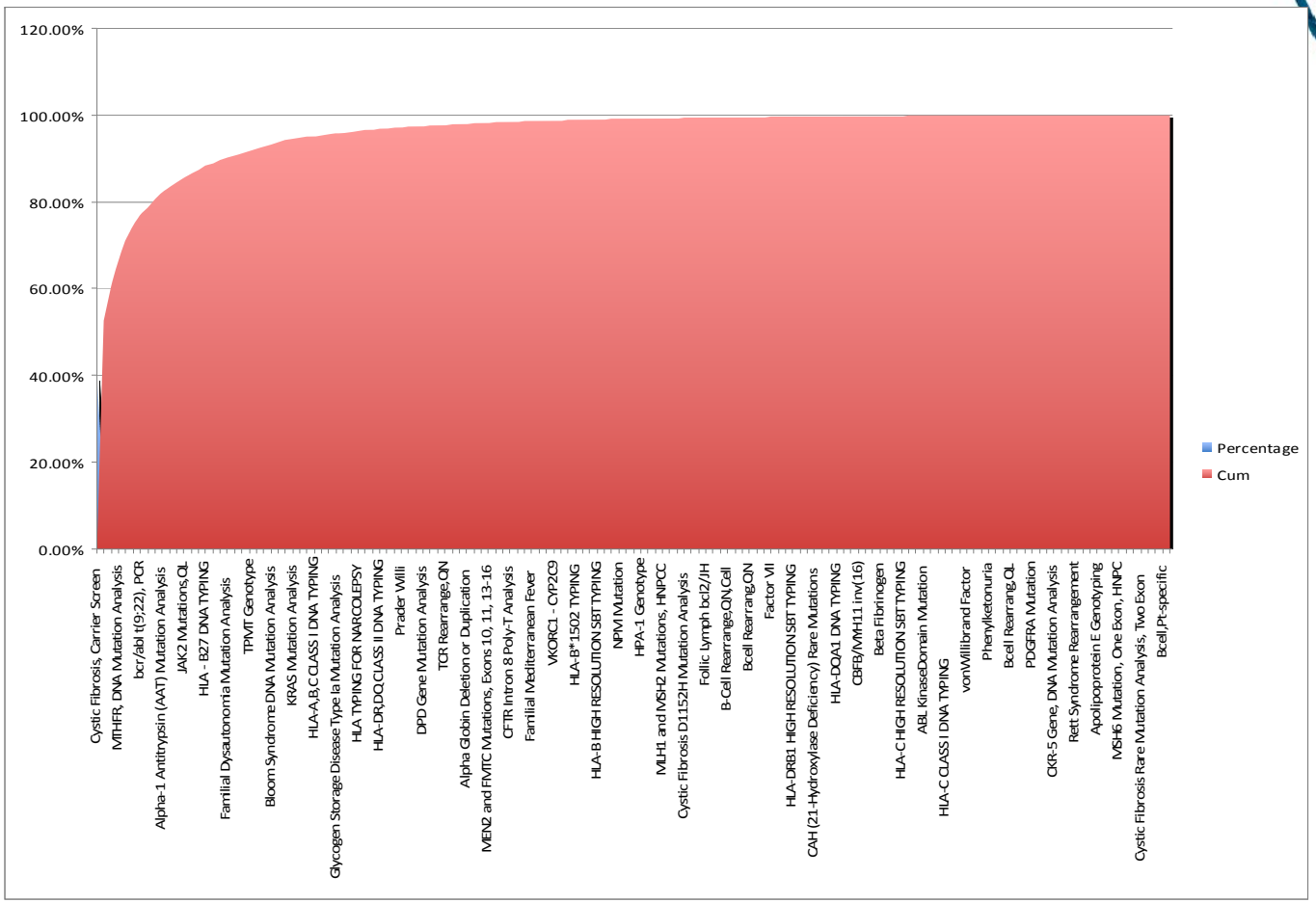
Creation of New AMA CPT codes for MolPath

- Tier 1 = analyte specific code
- Tier 2 = level of complexity code

- Genomic Sequence Procedures (GSPs)
- Multi-Analyte with Algorithmic Analyses (MAAAs)
- Proprietary Laboratory Assays (PLAs) (AKA PAMA codes)

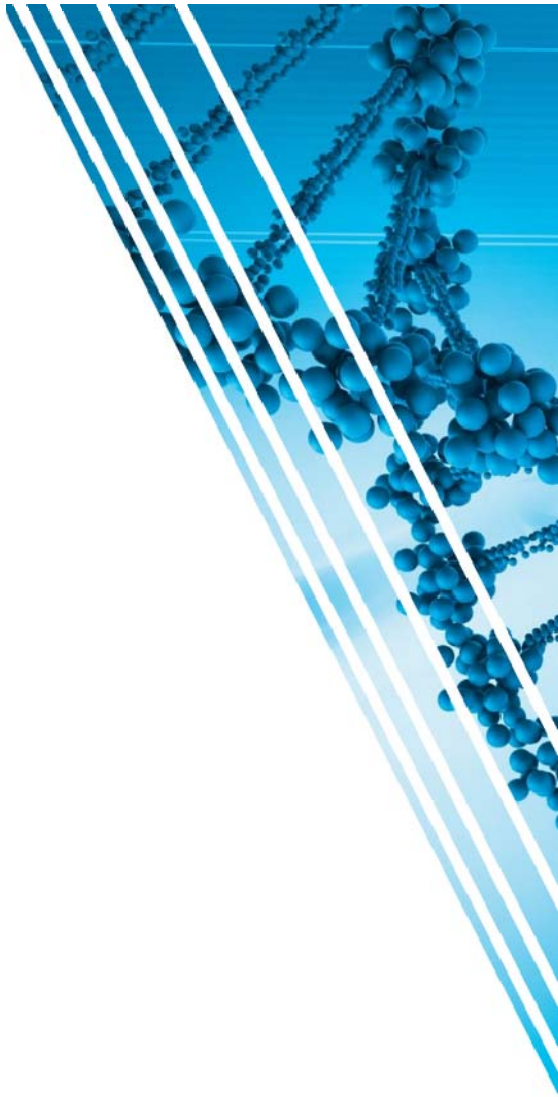


Relative Percentage of Tests from Labs 2009



CPT Tier 1 Descriptor

- *HUGO approved gene symbol (HUGO approved gene name)* (eg, disease state/condition) gene analysis; analysis type

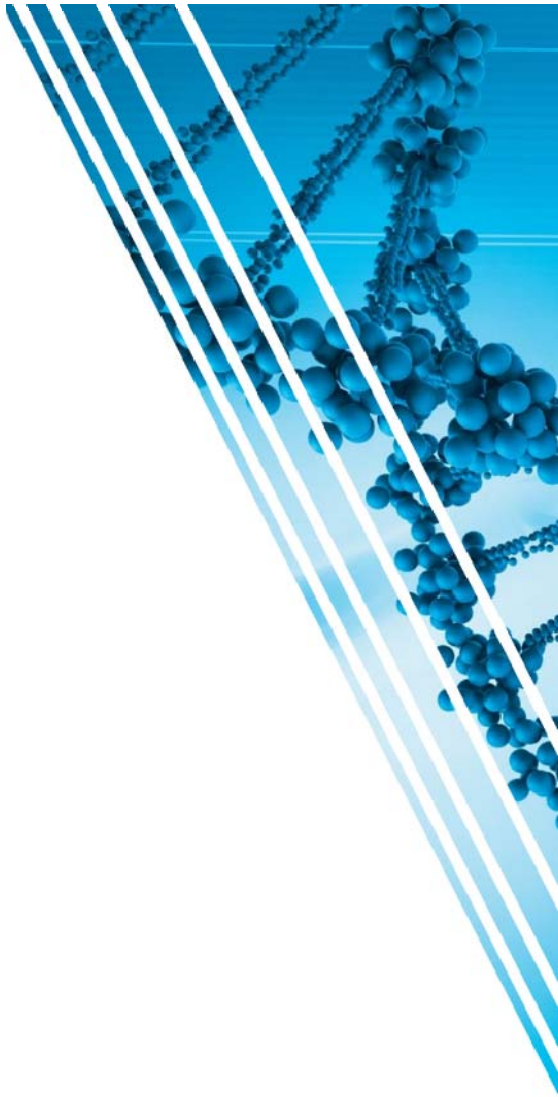


Descriptor Caveats

- Disease state/condition is not an all inclusive list – so ICD10 may not equate
- Common gene variant names are used
- The code includes all analytical services performed in the test (eg, cell lysis, nucleic acid stabilization, extraction, digestion, amplification, and detection)
- All analyses are qualitative unless otherwise noted

Tier 2

- Less common; lower volume assays
- Divided into 9 levels of complexity
- ~ 800 descriptors



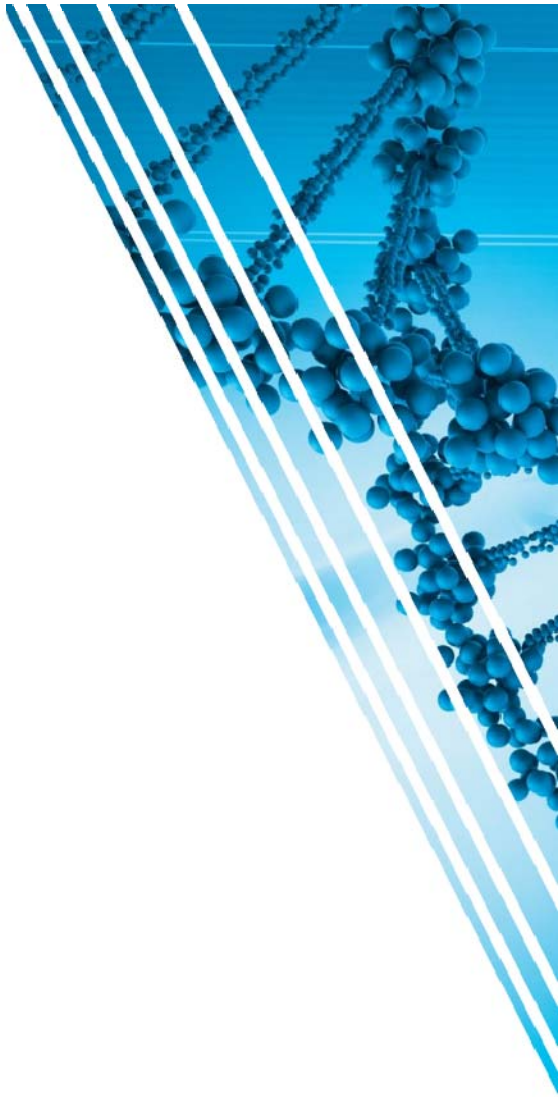
What do you do if your genes/analytes are not listed?

- 81479
- You cannot self assign
- You cannot use multiples of 81479
- Submit a coding change proposal (CCP)

Coding Change Proposal (CCP)

- Form available on AMA website
- References to document clinical validity
- Clinical vignette
- Description of service

- https://www.ama-assn.org/practice-management/applying-cpt-codes



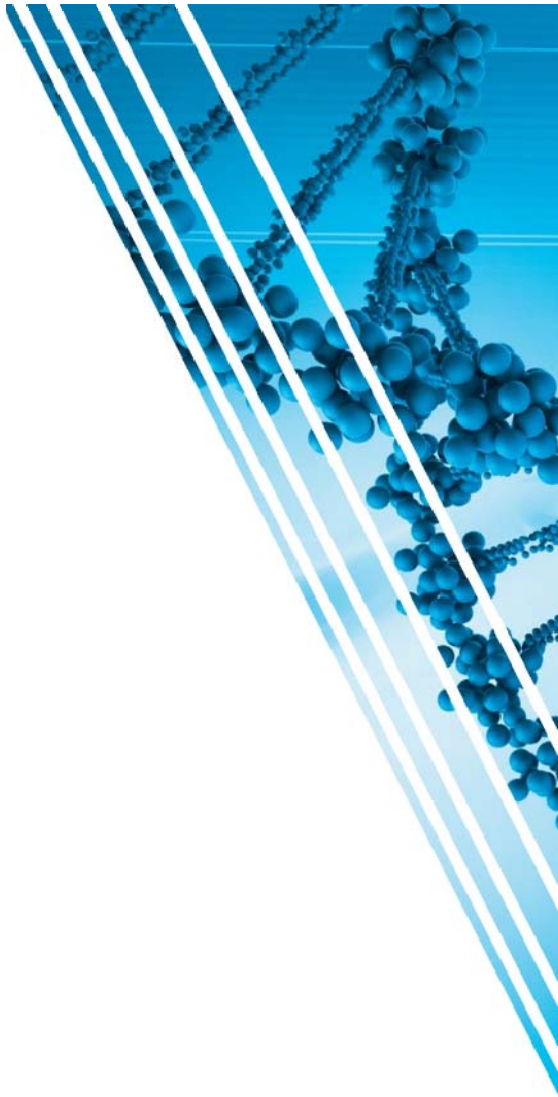
Where does NGS/Multi-Gene panels fit? – Genomic Sequencing Procedures (GSPs)

- AMP submitted a Coding Change Proposal (CCP) for Multi-gene panels
  - Separates report and interpretation from analytes
  - Provides mechanism for re-analysis
- AMA convened an open meeting for all to discuss
- AMA developed new CPT codes and first set was published in 2015

Questions

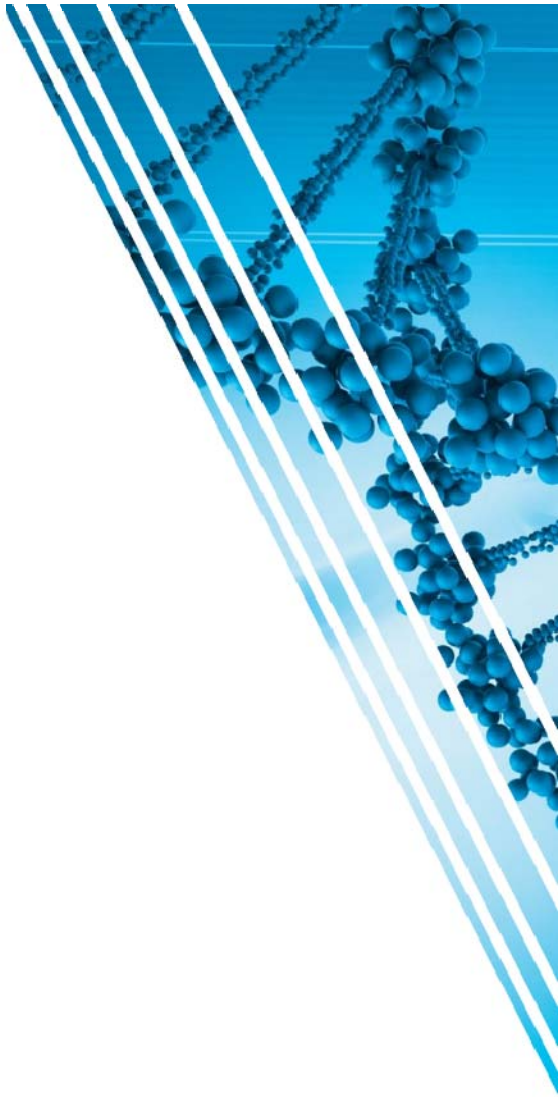
- Why didn’t each gene get its own code?
  - At the time; not enough available CPT codes
  - AMA now using non-contiguous codes
- Can a code be moved from Tier 2 to Tier 1
  - Yes; has to be requested by a Coding Change Proposal and approved by the AMA

REIMBURSEMENT

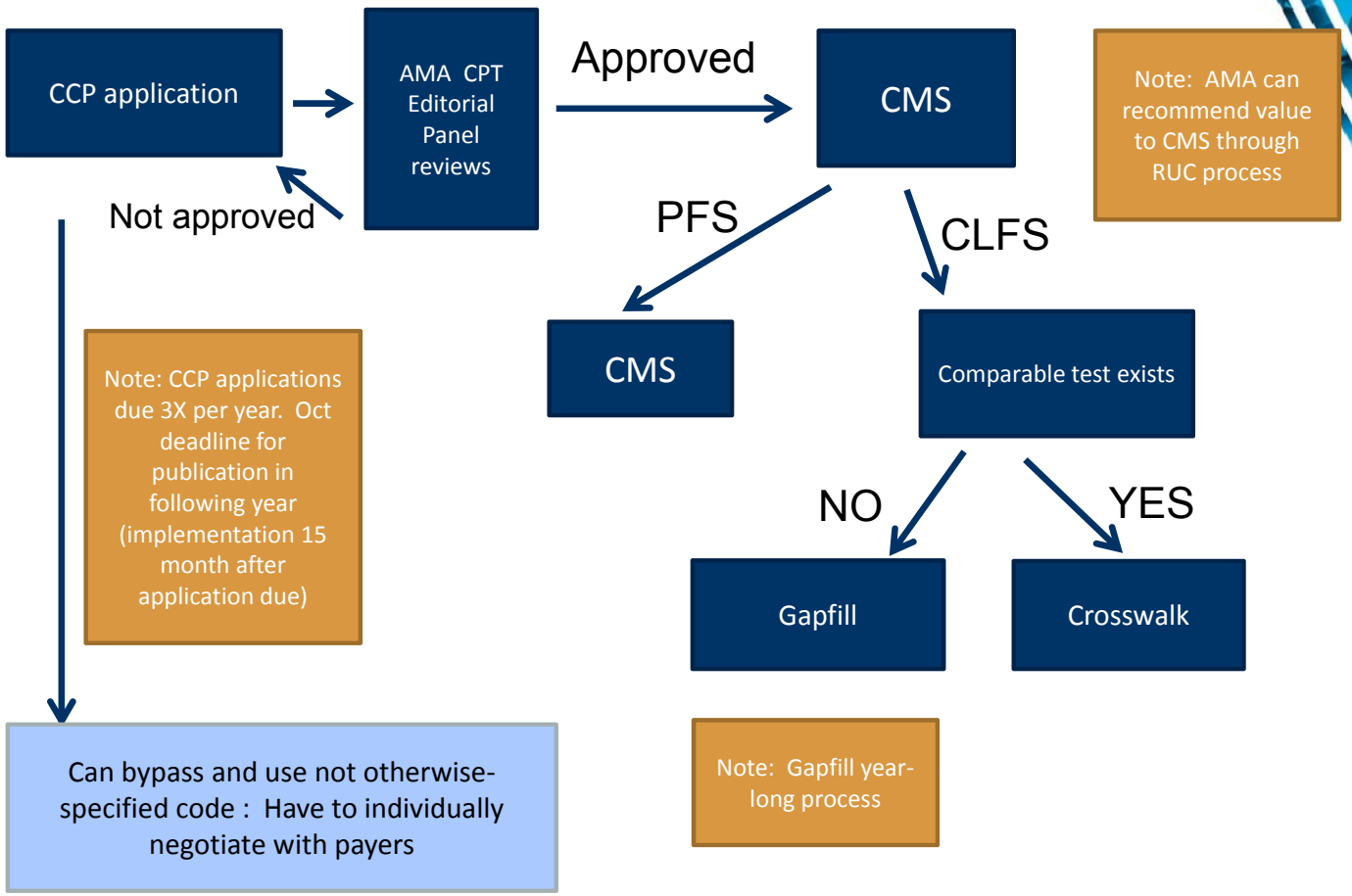


For those of you who have clinically billed pharmacogenetic tests, about what percentage of the time does insurance pay for part or all of the testing cost?

- 0%
- 25%
- 50%
- 75%
- 100%



CPT code and reimbursement determination



Physician fee schedule (PFS) vs. Clinical lab fee schedule (CLFS)

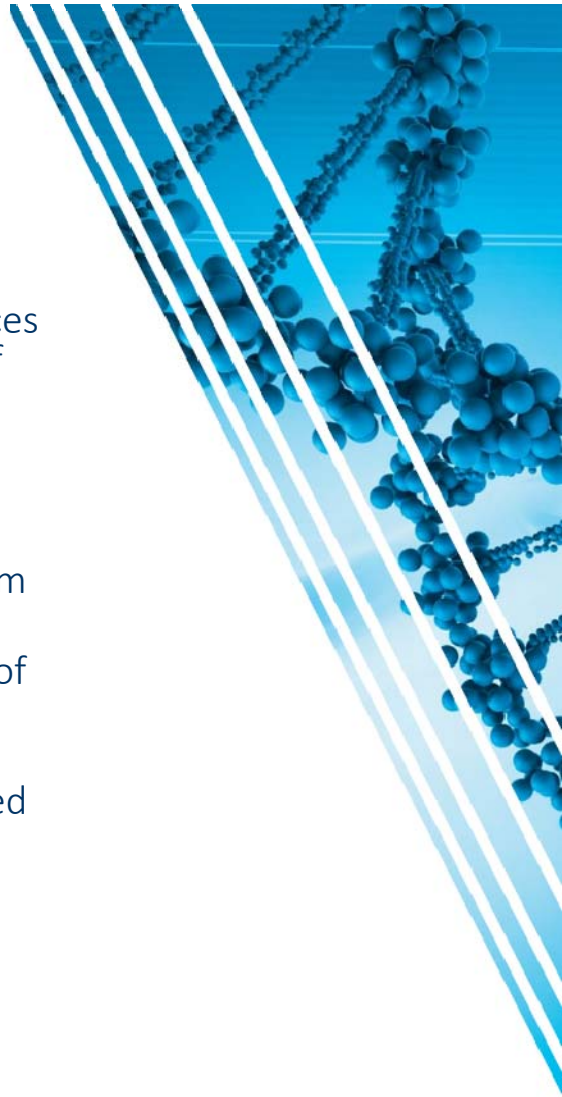
- Background
  - Molecular “stacking” codes were on CLFS
  - The RUC recommended PFS
    - Specialty Society Relative Value Update Committee (RUC) = AMA multi-specialty committee tasked with making relative value recommendations to CMS for new and revised codes, as well as annually updating relative value units (RVUs) to reflect changes in medical practice
  - Federal laws related to physician practice
    - MD vs PhD
    - Copays
    - Anti kickback rules
    - Physician signature requirements

- CMS placed all Molecular Pathology Tier 1 and Tier 2 codes on CLFS

PFS vs. CLFS – Physician practice

- 42 CFR 415.130 Physician pathology services. The carrier pays for pathology services furnished by a physician to an individual beneficiary on a fee schedule basis only if the services meet the conditions for payment in § 415.102(a)* and are one of the following services:
  - (1) Surgical pathology services.
  - (2) Specific cytopathology, hematology, and blood banking services that have been identified to require performance by a physician and are listed in program operating instructions.
  - (3) Clinical consultation services that meet the requirements in paragraph (c) of this section.
  - (4) Clinical laboratory interpretative services that meet the requirements of paragraphs (C)(1), (c)(3), and (c)(4) of this section and that are specifically listed in program operating instructions.

    - * 415.102(a) requires the services be ordinarily performed by a physician and directly contribute to the diagnosis of an individual patient.



PFS vs. CLFS – other requirements

- Placement of MolPath CPT codes on PFS:
  - Labs would have to collect 20% copays
  - Special signature rules not required of clinical laboratory tests, and
  - Medicare policies regarding physician kickbacks and purchased test rules different than those for clinical laboratory tests, and
  - Pathology tests are paid on a different, and much lower fee schedule, in the Medicare Hospital Outpatient setting, whereas clinical laboratory tests are paid on the same clinical laboratory fee schedule in this setting.
  - Indirect costs would be assigned on the basis of all pathologist indirect costs, including hospital-based pathologists and the mean indirect costs of pathology tests, dominated by the routine preparation of paraffin blocks and slides. These indirect costs likely far below the indirect expense of a molecular diagnostics center, with far more expensive staff, development, and QC costs.

Coding for Physician Interpretation and Reporting

- CMS created Healthcare Common Procedure Coding System (HCPCS) code G0452 (Molecular pathology procedure; physician interpretation and report) effective Jan 1, 2013
- This code allows physicians (MDs) to bill for interpretation and reporting services that go beyond the technical reporting of test results
- The code CANNOT be billed by non-physician geneticists or other lab personnel
  - The rates established for the Tier 1 and Tier 2 codes are meant to account for work performed by non-physician personnel, including PhD-certified geneticists
- In 2013, this code is reimbursed at $18.71 under the Medicare Physician Fee Schedule (MPFS)

2 methods for CMS to determine reimbursement on Clinical Laboratory Fee Schedule (CLFS)

- Crosswalk
- Gapfill

Crosswalking

- If test is comparable to an existing test
- CMS sets reimbursement of new test to existing test
- Assigned a local fee and corresponding National Limitation Amount (NLA)

Gapfilling

- CMS determines no adequate comparable
- Medicare carriers are instructed to Gapfill
  - Empirical process based on local pricing patterns
  - Medical Directors may meet and share information regarding the new test, though cannot reach a formal consensus.
- Approximate Timeline
  - April 30 - CMS posted interim contractor-specific amounts online
  - 60-day comment period on interim amounts (May-June)
  - CMS posts final contractor-specific amounts and National Limitation Amounts (NLA) online
  - CMS sets the NLA for each CPT code at the median of the contractor specific amounts
  - Reconsideration requests accepted for 30 days
  - Final NLAs made effective January 1 for the entire country

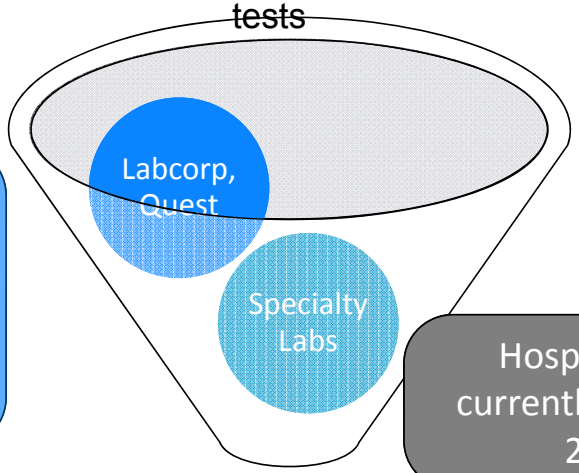
CMS posted (Gapfill) rates Tier 1 PGx Codes (CLFS2017)

HCPCS	Descriptor	National Limit	Mid Point
81225	CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)	$ 293.40	$ 293.40
81226	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *9, *10, *17, *19, *29, *35, *41, *1XN, *2XN, *4XN)	$ 454.07	$ 454.07
81227	CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)	$ 176.03	$ 176.03
81355	VKORC1 (vitamin K epoxide reductase complex, subunit 1) (eg, warfarin metabolism), gene analysis, common variants (eg, -1639/3673)	$ 0	$ 0
81381	HLA Class I typing, high resolution (ie, alleles or allele groups); one allele or allele group (eg, B*57:01P), each	$ 129.74	$ 129.74

Medicare Payment Process for Lab Tests is Changing Creating Some Uncertainty Around Future Payments (PAMA)

Starting in 2017, Medicare Payment Will Be Based on Commercial Payer Rates

Every 3 years, all labs submit commercial payment rate data for all lab tests



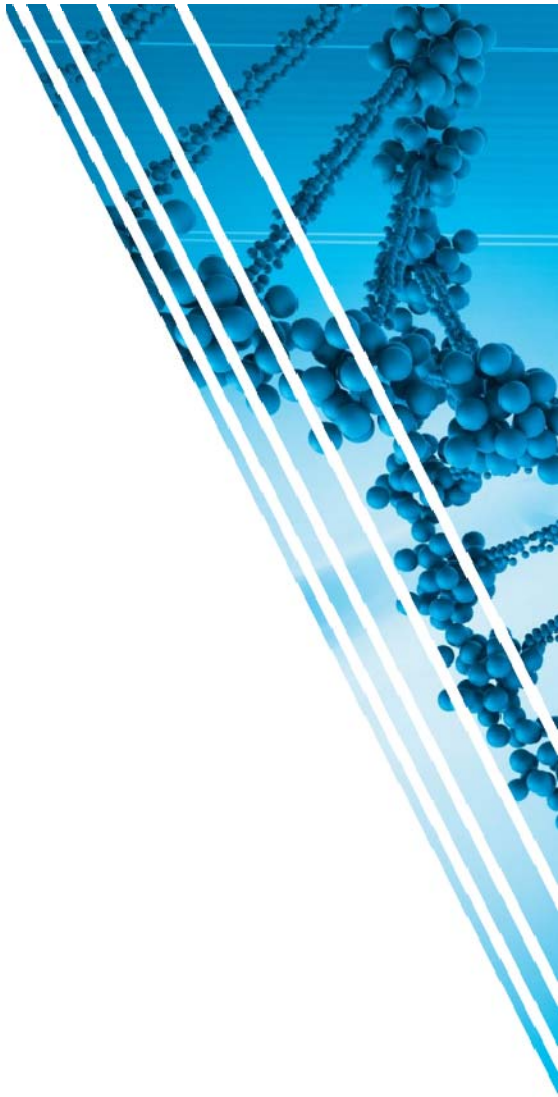
Maximum Medicare payment reduction of 10% year on year from 2017 – 2019, then 15% year on year from 2020 – 2022

Hospital Labs currently Excluded 2015

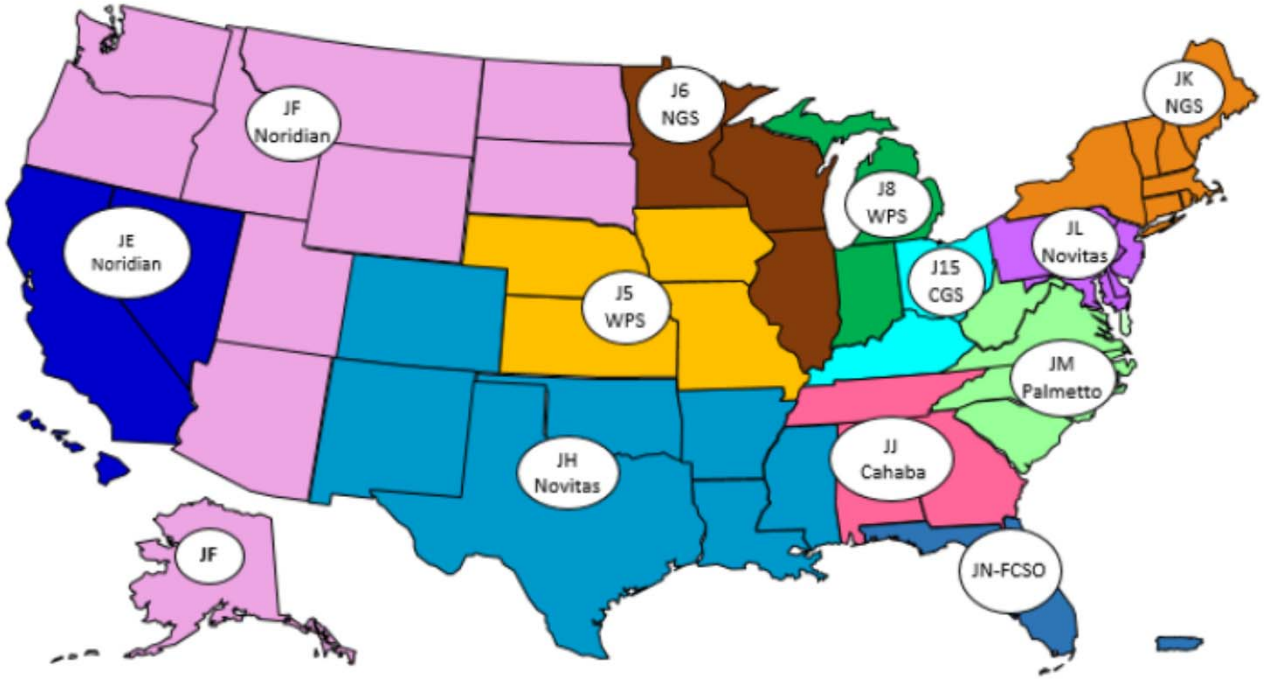
Median Commercial Payment = New Medicare Payments

Deluge of LCDs and Private Payer Coverage Policies

- CMS MACs issued 56 LCDs in 2015
- Unknown number of formal and informal private payer coverage policies
- Limited to no transparency on how decision was reached in final LCDs
  - Slightly better transparency on the private payer side but limited expertise available to evaluate evidence of clinical utility



Medicare Administrative Contractors (MACs)



http://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/MACJurisdictions.html

GSPs (Panels) Pose a Perceived Conundrum for Payers

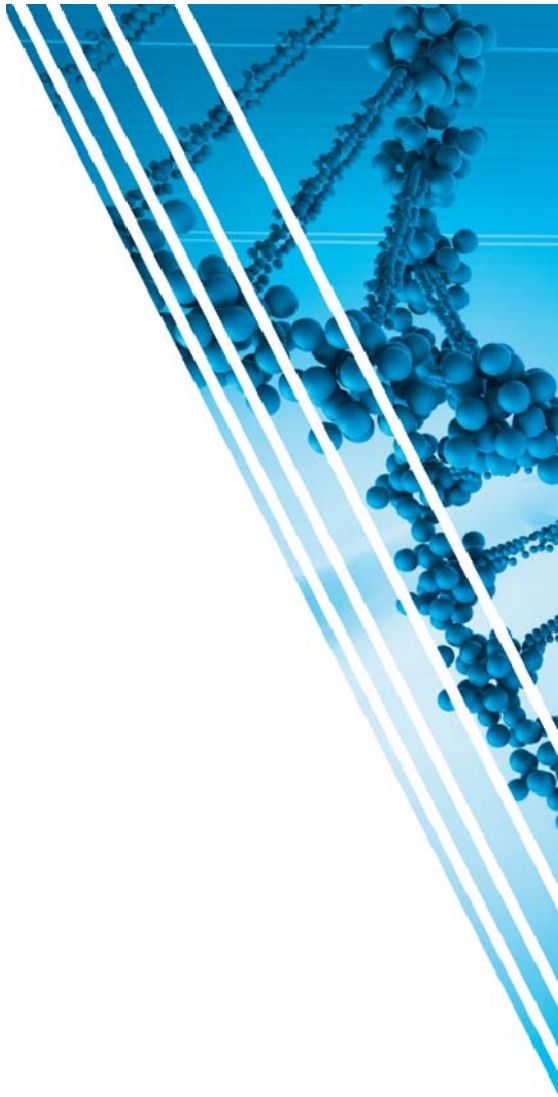
- Example: Payers in general see potential benefits for GSPs (panels) in certain patients with tumors
  - However many believe that inherent features of GSPs do not fit the medical necessity definition required for coverage, most view GSPs as a bundle of targets versus comprehensive characterization and prefer to evaluate each target individually (including coding and billing by individual Tier 1 codes), and many express skepticism regarding evidence, Quality of Life and hospice care uptake (Trosman JR et al J Natl Compr Canc Netw. 2015 Mar;13(3):311-8.)
  - Significant differences in the coding: some laboratories using single analyte Tier 1 codes (meeting clinical practice guidelines) some using 81445, others 81479, etc.

Cross-Walk Recommendations for Targeted Genomic Sequence Analysis (81445, 81450, 81455)

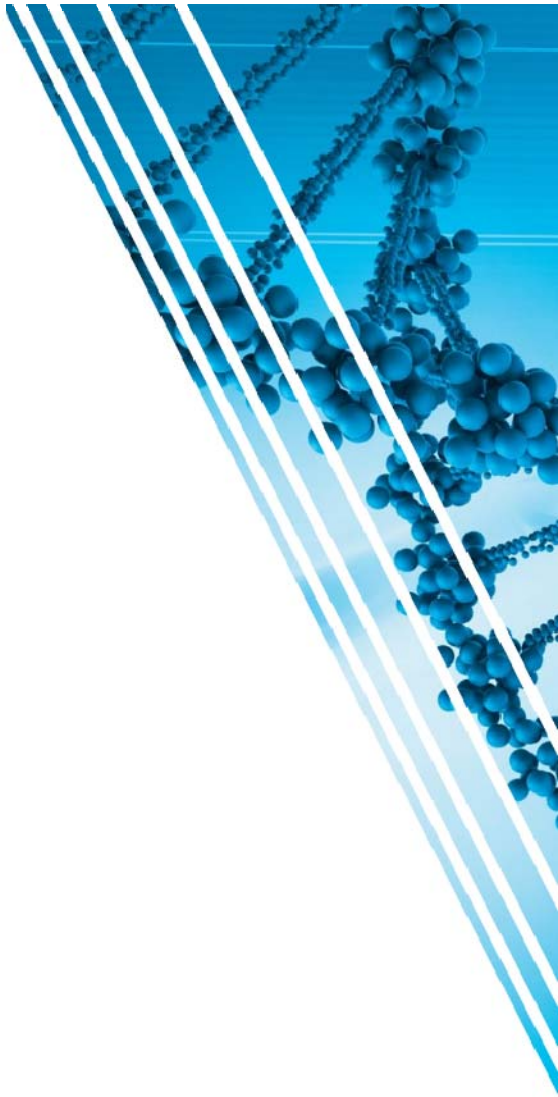
Code	CPT Descriptor	Rationale	Recommendation
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, 5-50 genes (e.g., ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if perfo	Median number of genes is (27) ln(27) = 3.29 **2016 National Limit: $597.91**	Crosswalk with multiplier 81292 x 3 87901 x 3 **Crosswalk Recommendation: $2,987.85**
81450	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA and RNA analysis when performed, 5-50 genes (e.g., BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants, and copy number variants or rearrangements, if performed, quantitative assessment of mutant allele levels,	Median number of genes is (27) ln(27) = 3.29 **2016 National Limit: $648.40**	Crosswalk with multiplier 81292 x 3 87901 x 3 **Crosswalk Recommendation: $2,987.85**
81455	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA and RNA analysis when performed, 51 or greater genes (e.g., ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed	Most laboratory GSPs include 100 genes ln(100) = 4.6 **2016 National Limit: $0**	Crosswalk to 81292 x 4.6 plus 87901 x 4.6

Protecting Access to Medicare Act (PAMA) 2014

- Designates up to 4 MACs (Medicare Administrative Contractors) to establish coverage policies
- Constrains Medicare from dropping prices for any given test (limited to 55% over 6 year period)
- New term: Advanced Diagnostics (ADLTs)

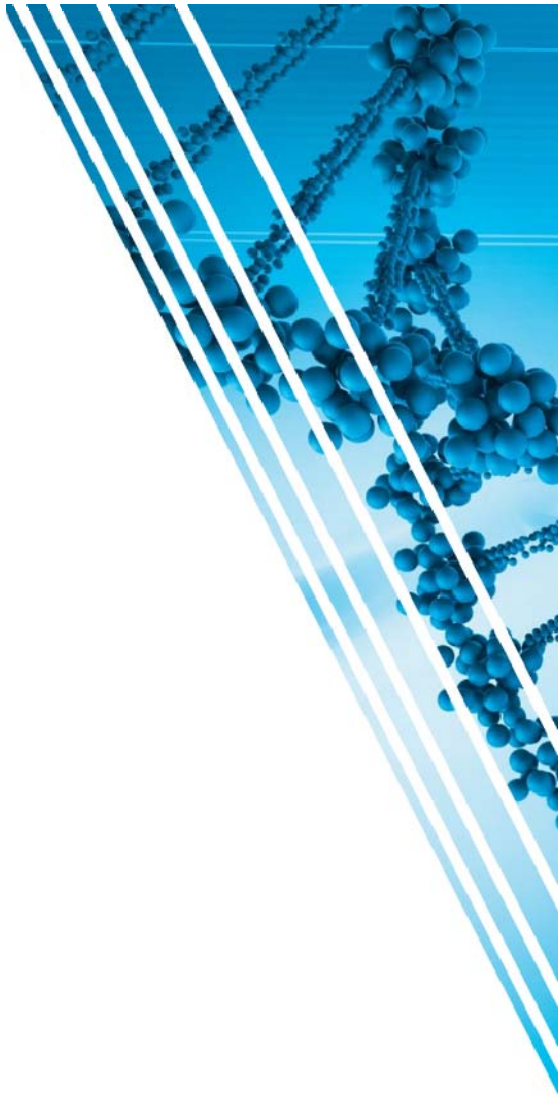


MACS AND LCD PROCESS

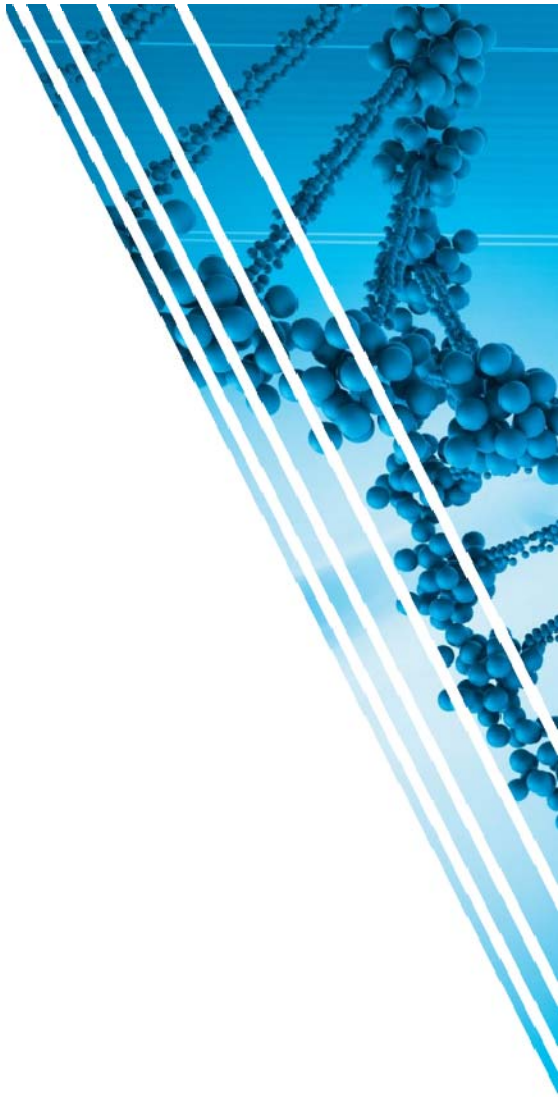


Local Coverage Determinations (LCDs)

- All new lab test coverage policies must be done through LCDs
- Draft LCD can be released at any time (not on CAC schedule)
  - CAC (Carrier Advisory Committee) meeting is optional
- Public comment period shortened to 30 days
- Final LCD becomes effective on issue date



REDUCTION IN PRICING

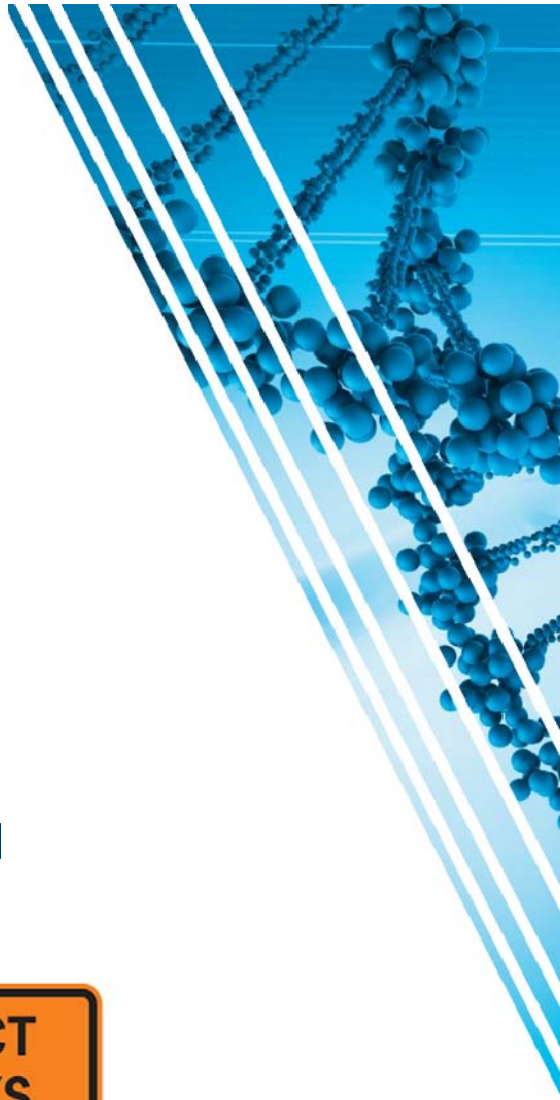


CLFS Payment rates

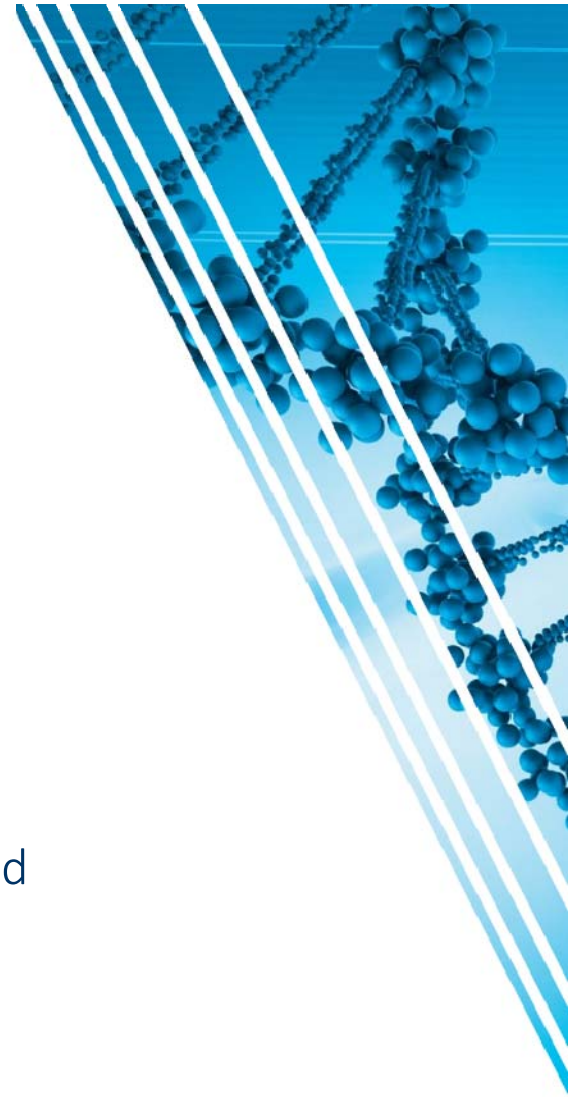
- Starting January 2018, rates will be derived from private payer rates (market based)
- CMS will establish a “weighted median” for each test by volume for each lab and payer
  - Reduction for a current individual test that exceed 10% will be phased in 2018-2023
- Labs must report testing volumes and reimbursement
  - Huge fines if fail to report ($10,000 per day for each failure to report)

“Applicable” laboratories

- Must reflect all discounts, rebates, coupons, and other price concessions
- Initial data collection period as January 1, 2016 to June 30, 2016
  - Annually thereafter
  - Based on reimbursement date (not billing date)
- CMS proposes to base reporting on a taxpayer identification number (TIN)
- Proposed Rule excludes from the definition any entity that is paid less than $12,500 per year on the Medicare CLFS



Reduction example



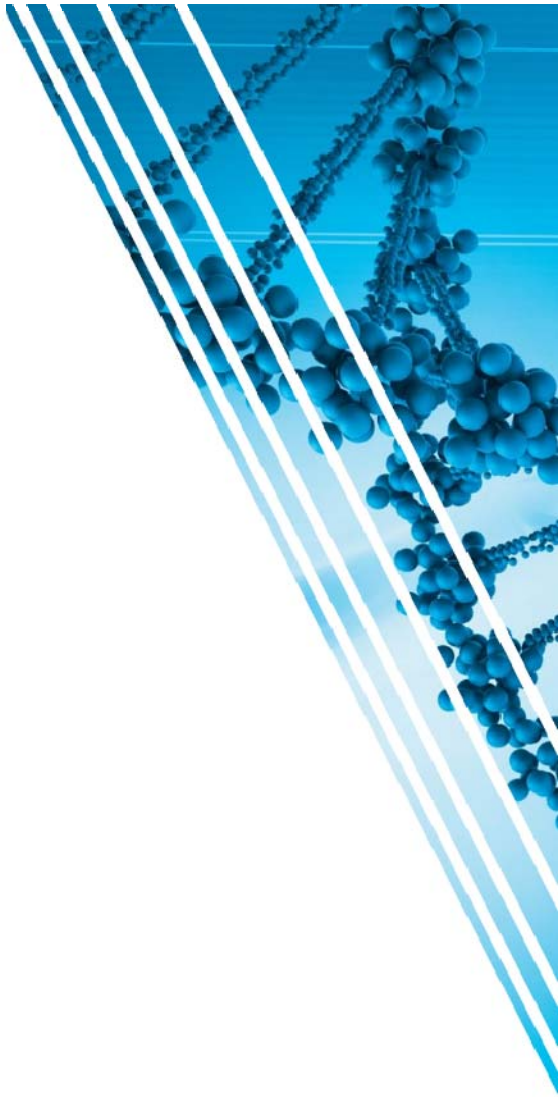
- Existing test is reimbursed on CLFS at $20.00 and the weighted median private payer rate is $15.00, then for CY 2018, the CLFS payment becomes $18.00 ($20.00-$2.00), the maximum 10% reduction from the current prices.
- CY 2019, a 10% reduction (-$1.80), lowering the payment to $16.20.
- The maximum reduction is applied to the prior year's payment until the reduction becomes less than the applicable percentage (10% or 15%) and the fee schedule payment goes to the weighted median of the private payer rates for the test.

Reduction in Pricing of Current Tests

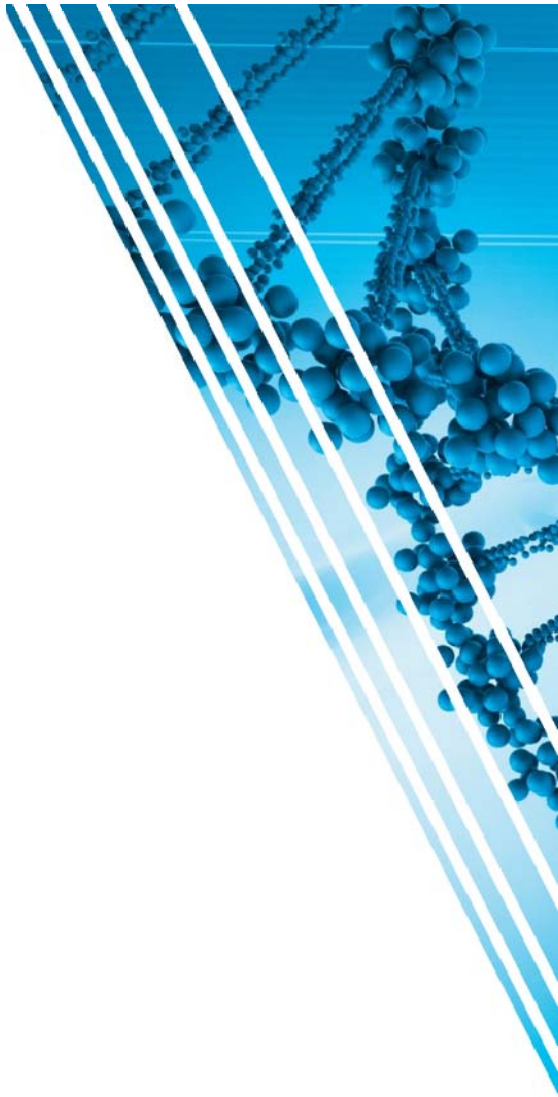
Year	Theoretical reimbursement	Reduction
2017	$100.00	10%
2018	$90.00	10%
2019	$81.00	10%
2020	$72.90	15%
2021	$61.97	15%
2022	$52.67	15%
2023	$44.77	15%

Increased reimbursement?

- Based on OIG (Office of the Inspector General) report, CMS believes that only reduction in reimbursement (https://oig.hhs.gov/oei/reports/oei-07-11-00010.asp)
- No discussion on increased reimbursement

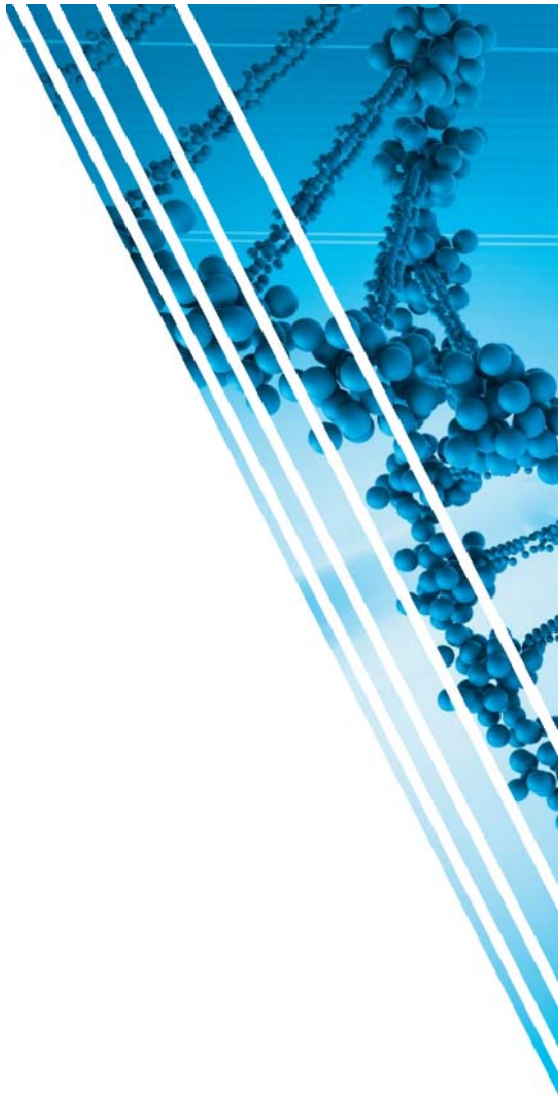


ADLT



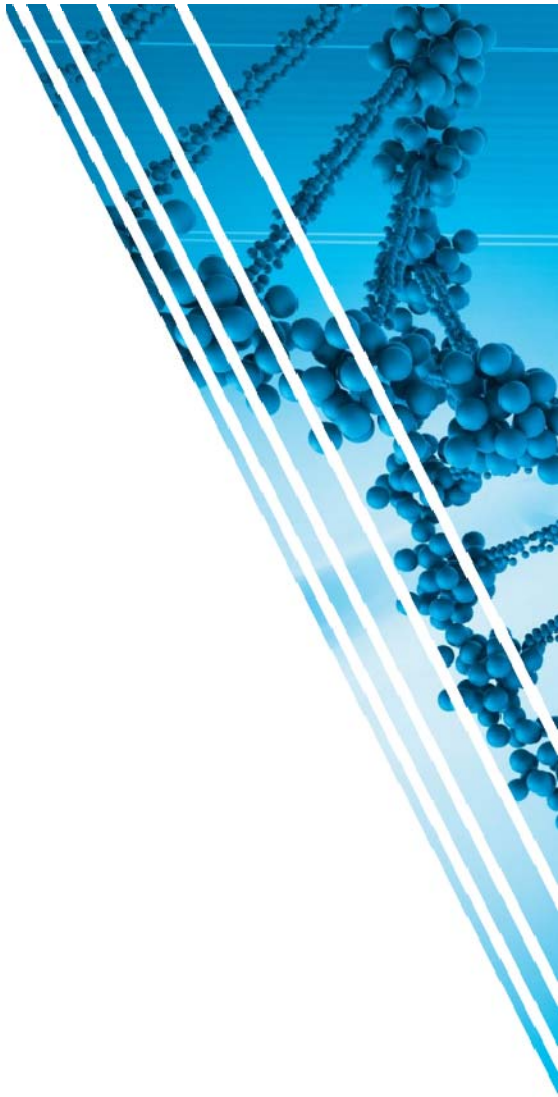
PAMA Advanced Diagnostic (ADLT)

- The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result
- The test is cleared or approved by the FDA
- The test meets other similar criteria established by the Secretary



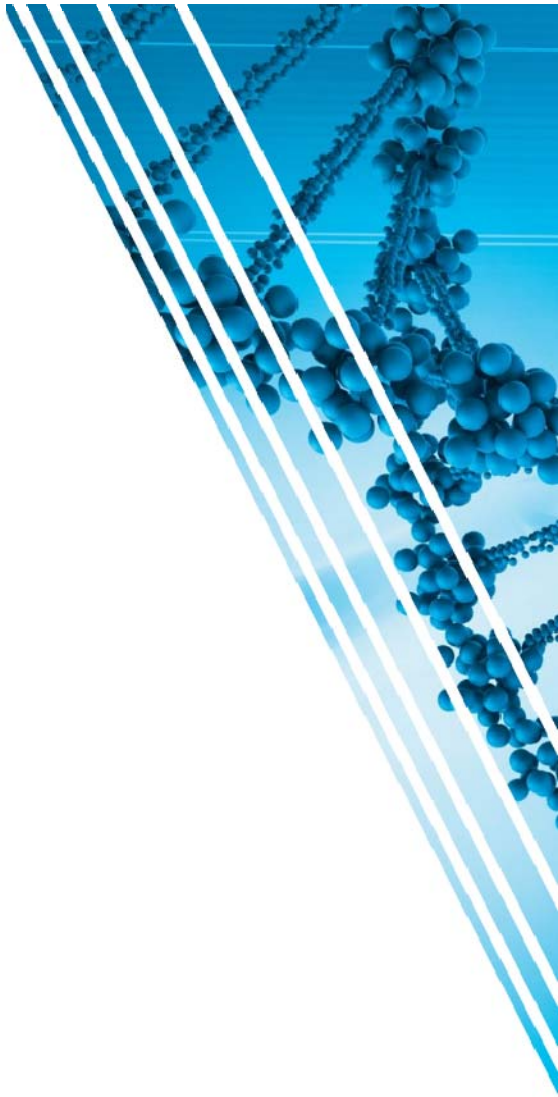
Advanced Diagnostics

- Typically single laboratory performs testing, often early stage companies
  - Resource intensive development costs (clinical trials, publication, guidelines)
- Reimbursement hurdles are high
  - Demonstrate analytical validity, clinical validity and clinical utility, physician utilization
  - Lack of granular coding
  - Complex billing rules
- Private payers and Medicare undertake lengthy coverage reviews
  - Pre-emptive non-coverage policies for new tests

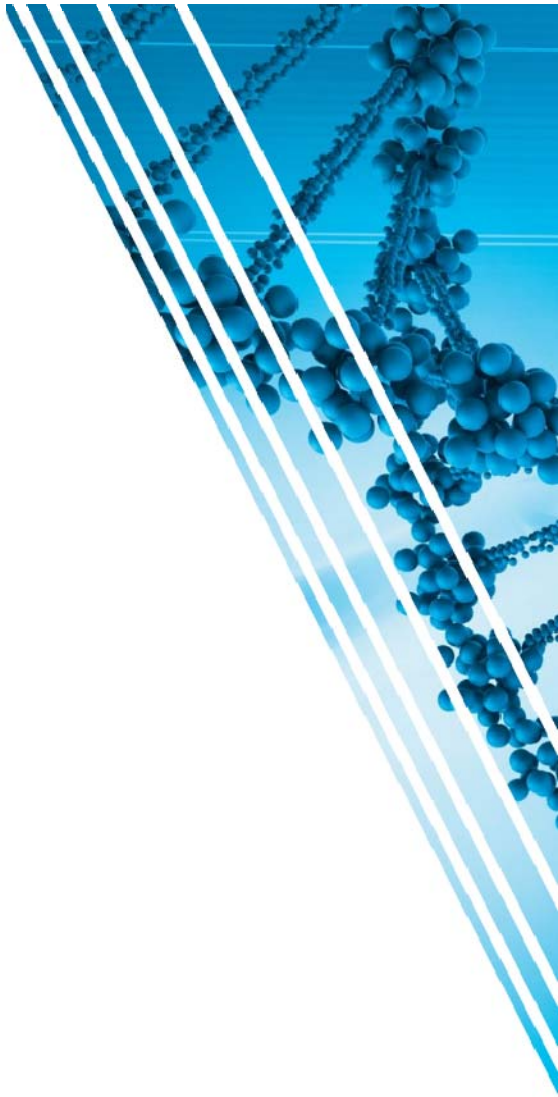


PAMA Advanced Diagnostics

- Established new transparent market-based payment method
  - 1st 3 quarters reimbursed at list
  - Application of market rates after initial period
    - Requires payback if overpriced
- Assignment of temporary HCPCS code
  - Enables ability to collect payer data
- Many details left to agency rulemaking



IN PATIENT BILLING

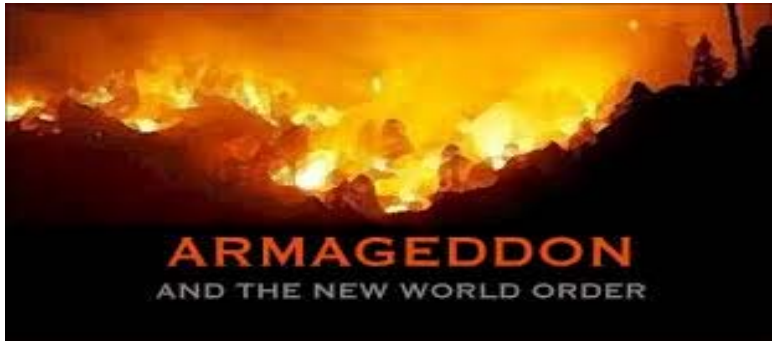


DRG: Diagnosis Related Group

- Classifying any inpatient stay into groups for the purposes of payment
- Hospitals are paid a fixed rate for inpatient services corresponding to the DRG group assigned to a given patient

Summary

- Did labs go out of business due to changes in CPT coding? YES
- Is there more granularity in coding? YES
- Reimbursement? DECREASED OVERALL
  - Many CPT codes have not been priced
- Are we done? NO



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