Downstream Outcomes of New Molecular Diagnostics CPT Coding System

Michael Watson, MS, PhD, FACMG
Advisory Committee on Heritable Disorders of Newborns and Children
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American College of Medical Genetics and Genomics
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Disclosures

- As Executive Director of the ACMG and the ACMG Foundation for Genetic and Genomic Medicine, I raise funds from industry in support of genetics education and training programs.
- No specific disclosures with regard to today's presentation.

Overview

- Billing and Coding 101
- Rate Setting
- Coverage Policy
- Recent Changes in CPT and their implications
- Needs

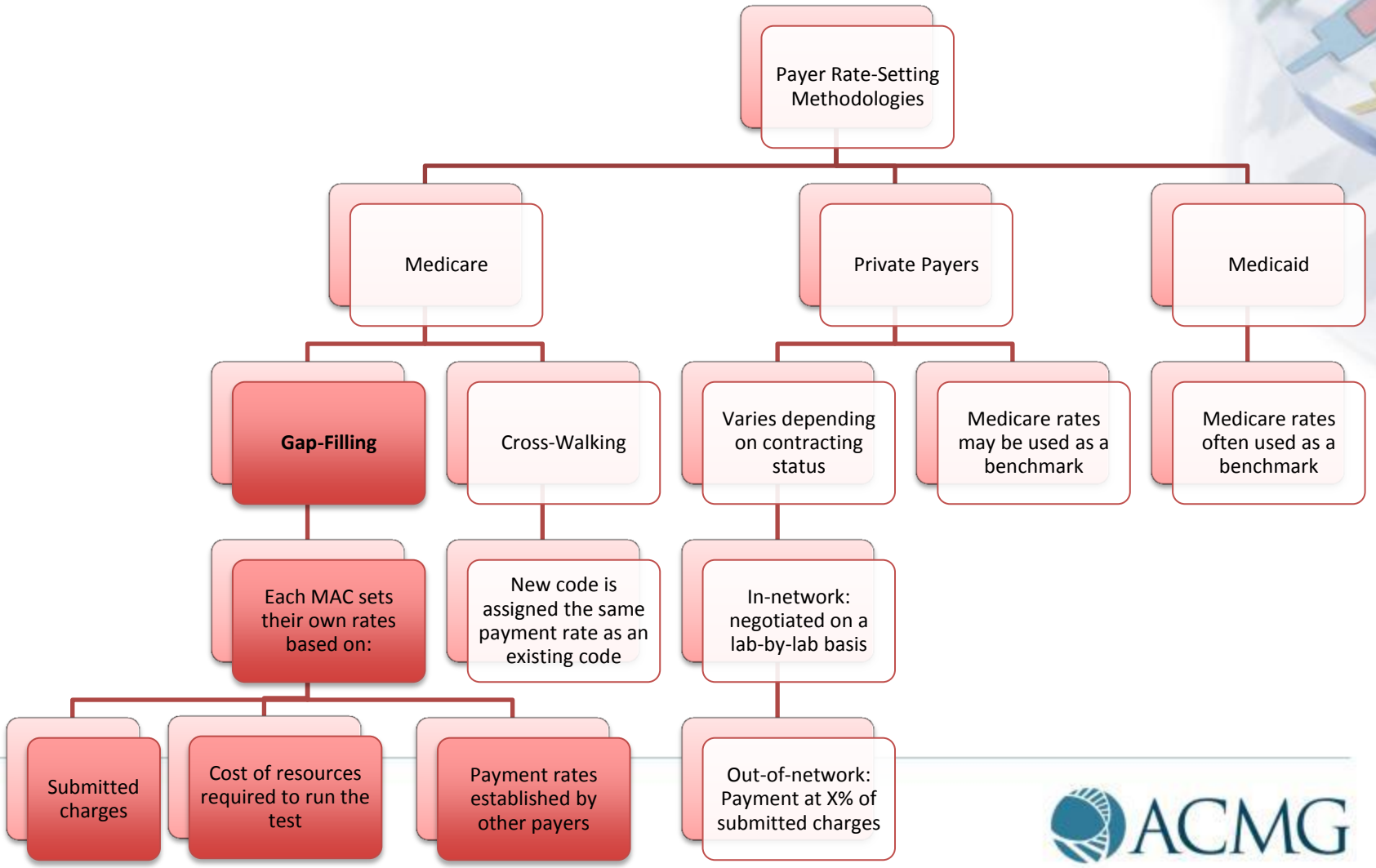
Billing, Coding, and Reimbursement 101

- Current Procedural Terminology (CPT)
  - Describes the clinical or laboratory services to be provided
  - Administrated through the AMA's CPT Editorial Panel
    - Includes significant evidence that is submitted with proposals for new CPT codes to allow Panel to determine appropriateness of assigning a CPT code
- International Classification of Diseases (ICD)
  - Describes the clinical indication for the service being provided and coded by CPT
  - WHO sponsored though US has an independent office

Pricing New CPT Codes: Clinical Laboratory Fee Schedule (CLFS) vs. Physician Fee Schedule (PFS)

- CLFS
  - Crosswalk:
    - Priced from already existing similar test
    - Price assigned by CMS but subject to all reductions imposed by Congress, or
  - Gap-fill
    - No similar code available.
    - Interactive price negotiation between local billing sites and payers

Overview of Different Rate-Setting Methodologies



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Pricing New CPT Codes: Clinical Laboratory Fee Schedule (CLFS) vs. Physician Fee Schedule (PFS)

- PFS
  - Survey of work (excludes liability and local cost of living costs) involved in new code by physicians practicing in area by comparing its work effort with other ‘similar‘ and already existing codes
- Price setting
  - Antitrust law and collusion in price setting impact what happens at national levels vs. local levels

Coverage Policy 1

- Currently a Local Coverage Determination (LCD) process
- Regulatory requirements
  - LCD should specify under what clinical circumstances the test is considered to be reasonable and necessary
  - A contractor shall develop a new or revised LCD when it identifies an item or service that is never covered under certain circumstances
  - Should be a public process with access to MAC Medical Director for questions

Coverage Policy 2

- When determined to be non-covered it can be
  - Statutory exclusion such as for screening tests; should only be applied to tests in asymptomatic people
  - Excluded pending determination of medical necessity and reasonableness (e.g. preauthorization or post-test negotiation)

Developmental History of New MolDx CPT Codes

- 1992 – 5 codes describing common methodologies in molecular diagnostic testing; code stacking
- 1997 – Due to severe limitations of a 5-digit coding system to absorb 1800+ new genetic tests with multiple clinical indications, codes remained methods based
- Overlaid a 2-digit alpha-numeric modifier to designate which of most commonly tested genes was the target
  - Payers refused to adjust computer systems to accommodate
- 2010 -2012 – In order to provide payers with more granularity as to the nature of the test, new coding system with gene and intended use of test was developed
  - Two tiers – Most common tests and with thousands more captured by levels (8) of test complexity

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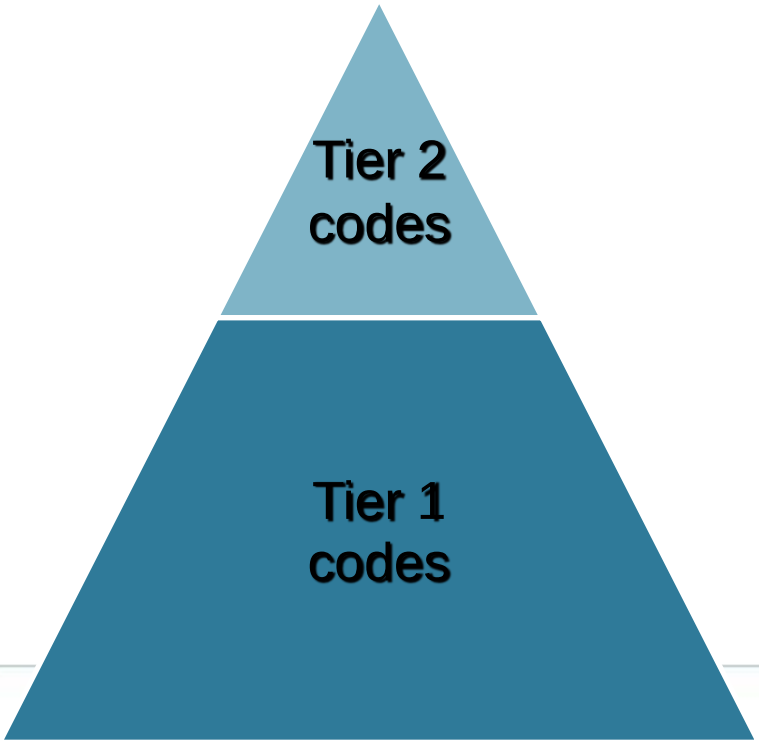
AMA CPT Panel Outcome

- **The AMA CPT Panel organized the MoPath codes into two general categories as Tier 1 and Tier 2 codes:**



Represent tests generally performed in lower volumes than Tier 1 procedures. The Tier 2 codes are arranged by nine levels of technical resources and interpretive work performed by the physician or other qualified health care professional.

Represent the majority of commonly performed single-analyte molecular tests.

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Tier 1 and 2 Test Examples (Excludes codes for multi-analyte algorithmic tests like free fetal DNA tests)

Tier 1 – Test specific

APC
BRAF
BRCA 1, 2 full sequence
vs. known targeted variant
CFTR
DMD
FMR1
Long QT
MECP2
SNRPN/UBE3A
HLA

Tier 2 – Complexity-based

Level 1 – single variant
Level 2 – 2-10 variants, 1 methylated or somatic variant
Level 3 - >10 variants, 2-10 methylated or somatic variants
Level 4 - sequence single exon
Level 5 – sequence 2-5 exons
Level 6 – sequence 6-10 exons
Level 7 - sequence 11-25 exons
Level 8 – sequence 26-50 exons
Level 9 – sequence >50 exons

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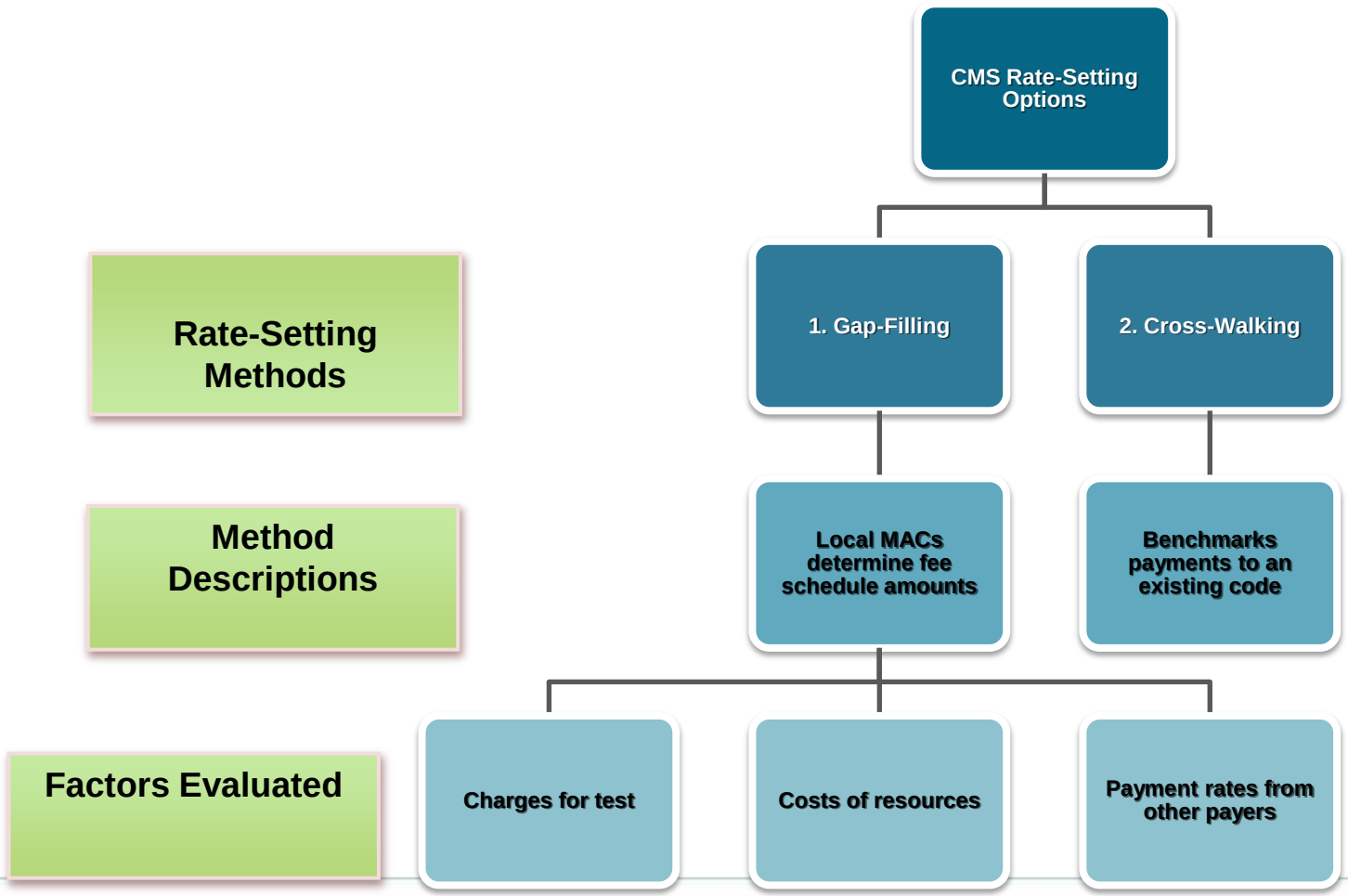
MolDx Coverage Decision-Making Process

- 2012 – First wave of new CPT codes developed by Molecular Pathology Advisory Group (MPAG) and ultimately approved by AMA CPT Editorial Panel with recommendation to CMS for placement on physician fee schedule

CMS Rate-Setting Options



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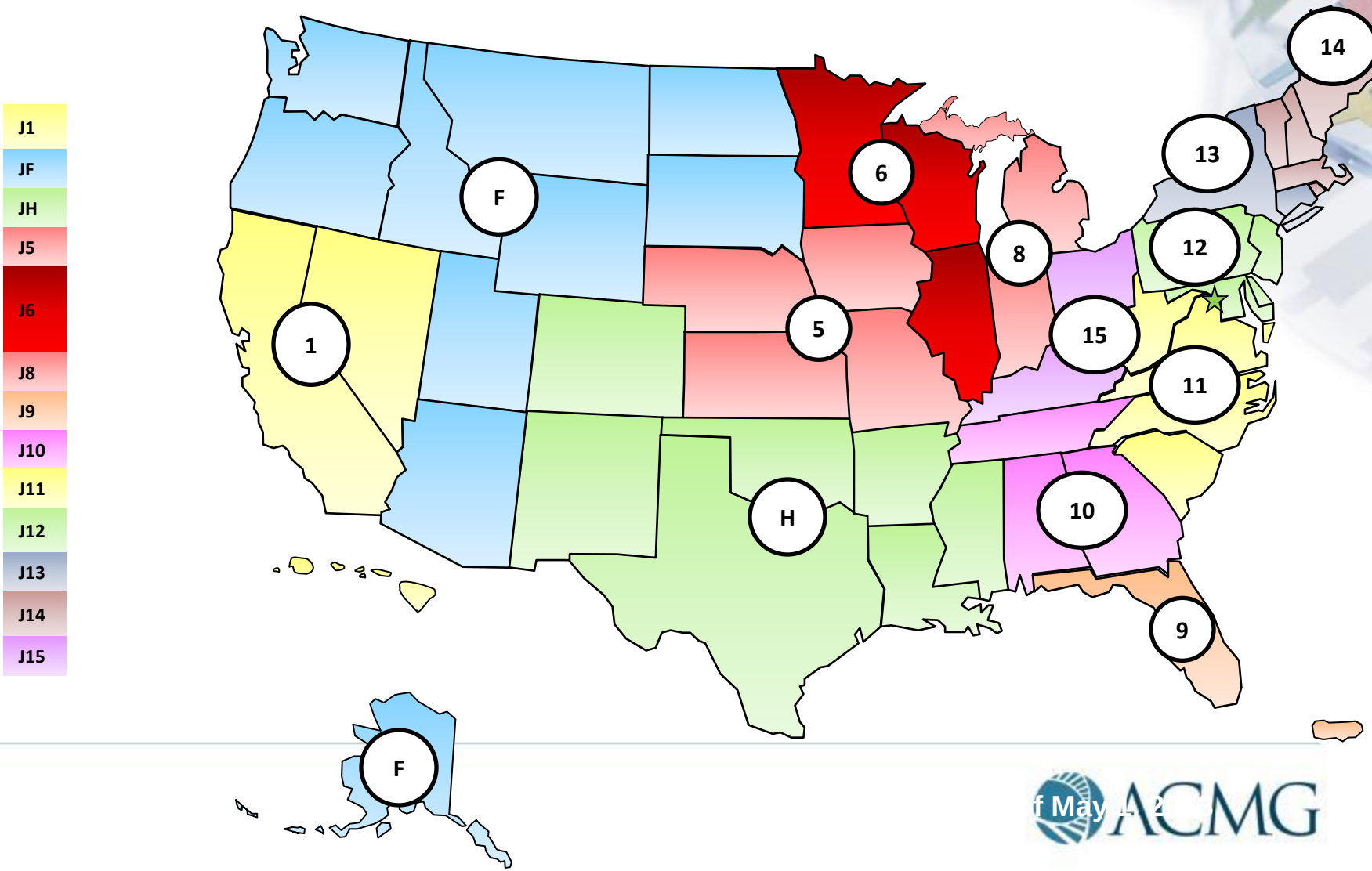
Medicare Administrative Contractor (MAC) Landscape*



Coverage Decision-Making Process

- 2013 – CMS places codes on CLFS and initiates biggest gap-fill of all time
  - Overwhelmed MACs; limited understanding of genetic tests and too many to address in 6 months
  - Pricing significantly biased by large national laboratories who began including new codes with old in bills in November 2013
- MACs overwhelmed

Sampling of Proposed MAC Gap-Fill Rates

- Proposed gap-fill rates for some commonly performed molecular pathology tests are listed below
- Please refer to the CMS website to view all proposed rates: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Gapfill-Pricing-Inquiries.html

Test	CPT Code	Palmetto	Novitas	First Coast	Cahaba	NGS/ WPS	Noridian/ CGS/ NHIC
Cystic Fibrosis	81220	$800.46	$1,343.57	$1,004.30	$1,200.00	N/A	N/A
Molecular Cytogenomics	81228	$646.14	$646.14	$646.14	$123.00	N/A	N/A
	81229	$675.56	$675.56	$675.56	$2,900.00	N/A	N/A
Fragile X	81243	$60.51	$60.51	$67.06	$123.00	N/A	N/A
	81244	$100.09	$100.09	$100.09	$123.00	N/A	N/A
Short Tandem Repeat Analysis	81265	$414.94	$414.94	$339.58	$123.00	$470.24	N/A
Hematopoietic Stem Cell	81267	$149.72	$149.72	$335.86	$123.00	$149.72	$149.72
Long QT Syndrome	81280	N/A	N/A	$3,140.90	$123.00	N/A	N/A
Prader-Willi; Angelman	81331	$73.22	$73.22	$58.31	$50.00	N/A	N/A

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Coding for Physician Interpretation and Reporting

- CMS created the Healthcare Common Procedure Coding System (HCPCS) code G0452 *(Molecular pathology procedure; physician interpretation and report)*[1]
  - This code allows physicians to bill for interpretation and reporting services that go beyond the technical reporting of the test results
  - The code can NOT 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)

HCPCS G0452 can be billed for molecular diagnostic interpretation and report when performed by a physician only

[1] http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-CY2013-Final-Payment-Determinations-11052012.pdf

Example:
FMR1 Non-Coverage Statement*

"Palmetto GBA has determined that Fragile X testing is not a Medicare covered service. Screening in the absence of signs and symptoms of an illness or injury is not defined as a Medicare benefit. Therefore, Palmetto GBA will deny testing for Fragile X as a statutorily excluded service."

http://www.palmettogba.com/palmetto/MolDX.nsf/DocsCat/MolDx%20Website~MolDx~Browse%20By%20Topic~Non-covered%20Tests~94DN6Z7803?open&navmenu=Browse^By^Topic||||

- **The Statutory Exclusion is applied to**
  - **the initial test (CPT Code 81343) as well as**
  - **the second test (CPT code 81244) which is additional testing performed when an abnormality has been identified on the first test (diagnostic testing)**

http://www.ncbi.nlm.nih.gov/books/NBK1384/

http://www.nature.com/ejhg/journal/v19/n9/full/ejhg201155a.html

How it’s Playing Out

MolDx Tech Assessments Do Not Follow the Required Process

MolDx Decisions…

- Posted on Internet, (some) *after* effective date
- Not included in Medicare Coverage Database
- Circumvents requirements for public notice & comment
- Decision re: SE cannot be appealed
- No transparency re: medical evidence review
- No CAC input
- CPT codes assigned without following established coding rules

Overly Broad

Of the 49 statutory exclusion (SE) decisions posted:

7 Based on testing in asymptomatic persons

4 Used to confirm a diagnosis

6 Alternate testing available

2 Clinical reasons – would approve on case by case review on appeal

6 Test has both diagnostic and screening use

16 Insufficient medical evidence

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Immediate Impact on Labs and Access [1]

- Many tests were not priced
  - Unclear for a very long time as to whether covered or not
- Labs weren't paid for most of first 6 months of 2013
  - Optimistically assumed that changes in coverage policies would return to 2012 status
  - One large national lab submitted $1 million in bills to Medicare in 2013 and received about $68,000 in return
  - Signature Genomics, a cytogenomic array testing lab, closed in April 2014
  - Parkview Lab in Indiana closed 2013

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Immediate Impact on Labs and Access 2

- All tier 2 tests being considered research rather than just a lot of rare disease tests for which space limitations in CPT preclude listing individually
- Preauthorization of genetic tests being required unless statutorily excluded
- Our assessment shows that Palmetto established noncoverage through web site statements and that in only 7 of 49, was the test only used in asymptomatic people

Collateral Damage 1

- Payers re-opened coverage policies in light of their better understanding of intended use of tests
  - However, ignored legislated requirements for coverage policy decision-making that include public hearings and ready availability of MAC Medical Directors to
- Laboratories closing
  - Loss of small academic labs directly impacts innovation
- Access to diagnostic testing being lost
- Training programs beginning to close

Collateral Damage 2

- Tests that are “statutorily excluded” cannot be appealed; further, have not been priced
- Medicaid, private payers looking to Medicare for input on pricing these tests
- State Medicaids no longer covering and paying for medically necessary tests
- Incomplete picture of medical evidence used in decisions, with no transparency
- Expansion of MolDx decisions to other MAC jurisdictions → no opportunity for refinements
- *De facto* national coverage decisions – without following the statutory NCD process

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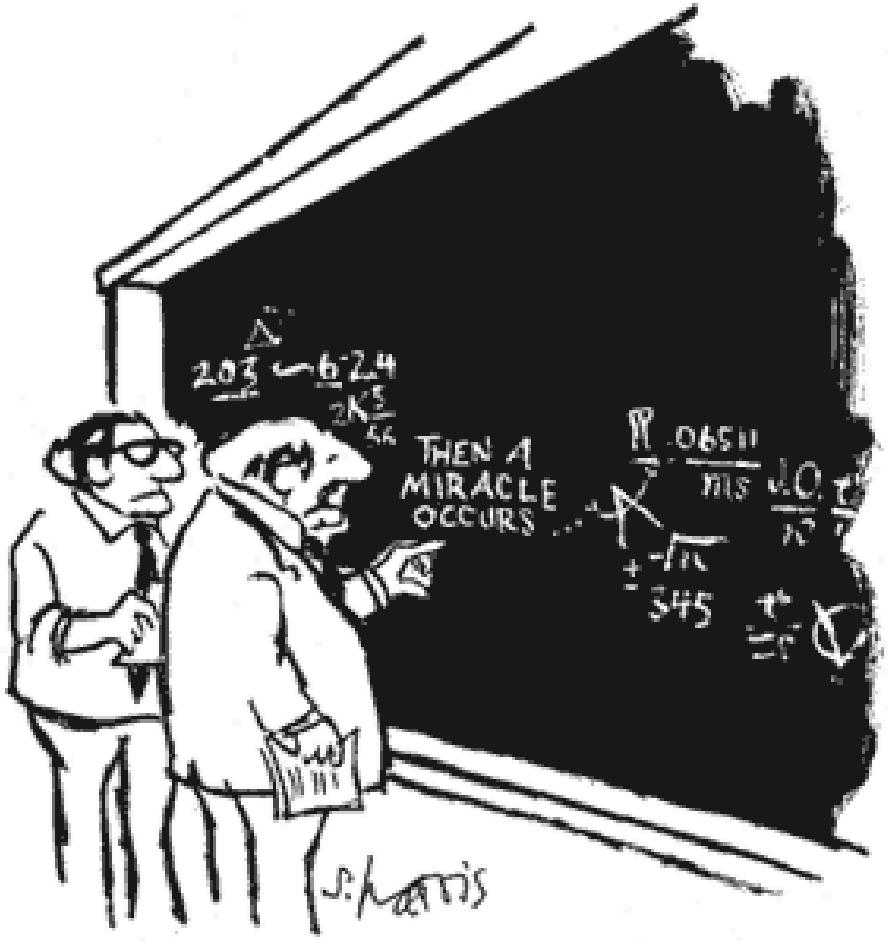
Problems Extending to Medicaid

- Numerous State Medicaid Programs are following the CMS MACs outcome
  - Excluding cytogenomic array testing
    - Standard of care based on ACMG and ACOG guidelines
    - Reasons for denial range from claiming its:
      - Research
      - Screening
      - Lacks utility
    - Ignores cost of diagnostic odyssey and utility to families

Where is the Disconnect?

$1000 Personal Genome



"I THINK YOU SHOULD BE MORE EXPLICIT HERE IN STEP TWO."

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Raising the Bar on Justification for Reimbursement of Tests

- No inherent utility in having a diagnosis
- No inherent utility in physician altering management based on knowledge of diagnosis

- Utility is from showing change in outcome based on having a diagnosis and altering management
  - Very hard to get robust statistical answers for rare diseases

- Even with utility shown, preference being given to FDA approved tests at expense of laboratory developed tests
  - Obfuscating test coding (NOS coded if FDA approved)

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Protecting Access to Medicare Act 2014 (PAMA)

- Became law on April 1, 2014 to fix the Sustainable Growth rate (SGR) formula
- Most significant change to clinical laboratory Industry since CLIA in 1988
- Changes:
  - how billing codes are developed
  - coverage guidelines
  - price setting
    - Requires clinical labs to report to CMS the the volume of each lab test and the price paid by private payers to inform CMS price setting
    - Reductions of up to 75% by 2022 are possible
    - If capitated care contracts are excluded, the big private labs win.

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Implications of Pricing Genetic Tests by Lowest Common Denominator

- Lethal blow to rare disease diagnostic testing
- Lethal blow to innovation as small academic labs close up
- Lethal blow to local testing

Multi-specialty Coalition Formed

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ASCLS

ASCP American Society for Clinical Pathology

ASHI
American Society for Histocompatibility & Immunogenetics
www.ashi-hla.org

AMP
Association for Molecular Pathology

College of American Pathologists

cap

represent 150,000 medical professionals engaged in molecular diagnostic testing

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Concerns

- The MolDx program does not follow LCD requirements for transparency, stakeholder input, and medical evidence

- As a result, Medicare is denying beneficiaries' access to tests that are:
  - reasonable and necessary
  - used for diagnosis of symptomatic patients
  - used to diagnose cancer, other common (cystic fibrosis) & rare (fragile x) diseases
  - used to select & monitor therapy

Recommended Changes

- **Limit the application of "statutory exclusion" to screening of asymptomatic patients**
  - **Publish an Article to address this non-coverage for statutory exclusion along with the appropriate ICD-9 codes to be submitted, e.g. V 82.7 - screening for genetic disease carrier status**
  - **Then codes that were not priced due to coverage concerns can be priced by the MACs.**
- **Pay claims for molecular pathology tests, unless an LCD exists that specifically states that a test is not covered. If no LCD for a test exists, Medicare should send claims for manual review of *whether the test is 'reasonable and necessary' for the individual patient.***
- **Follow the coverage determination/LCD process and develop policies to define medically "reasonable and necessary" criteria**

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Recommended Changes

- Restrict Medicare contractors from adopting the MolDx program in jurisdictions that have not already done so
- Follow correct coding so that appropriate pricing can be determined
- Reopen and re-adjudicate claims previously denied for statutory exclusions and/or multiple services performed on the same day ("panels") to allow coverage and payment
- Address coverage and payment for multi-analyte assays which include an algorithmic component (MAAAs)
- Need a registry system to aggregatae data on rare diseases
  - Refrain from pursuing Coverage with Evidence Development Process until CMS has defined appropriate criteria for application at the local level, through a transparent process that allows public comment.

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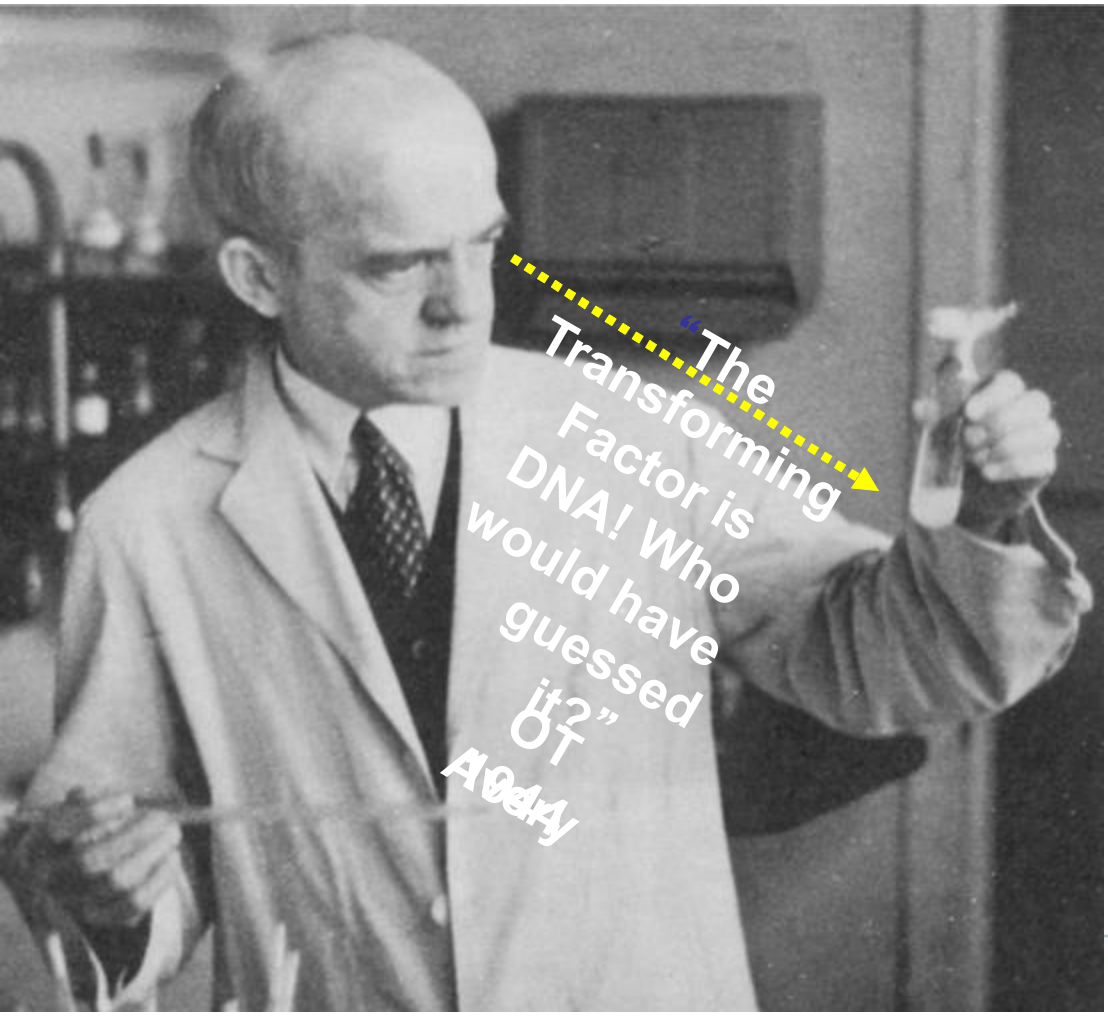
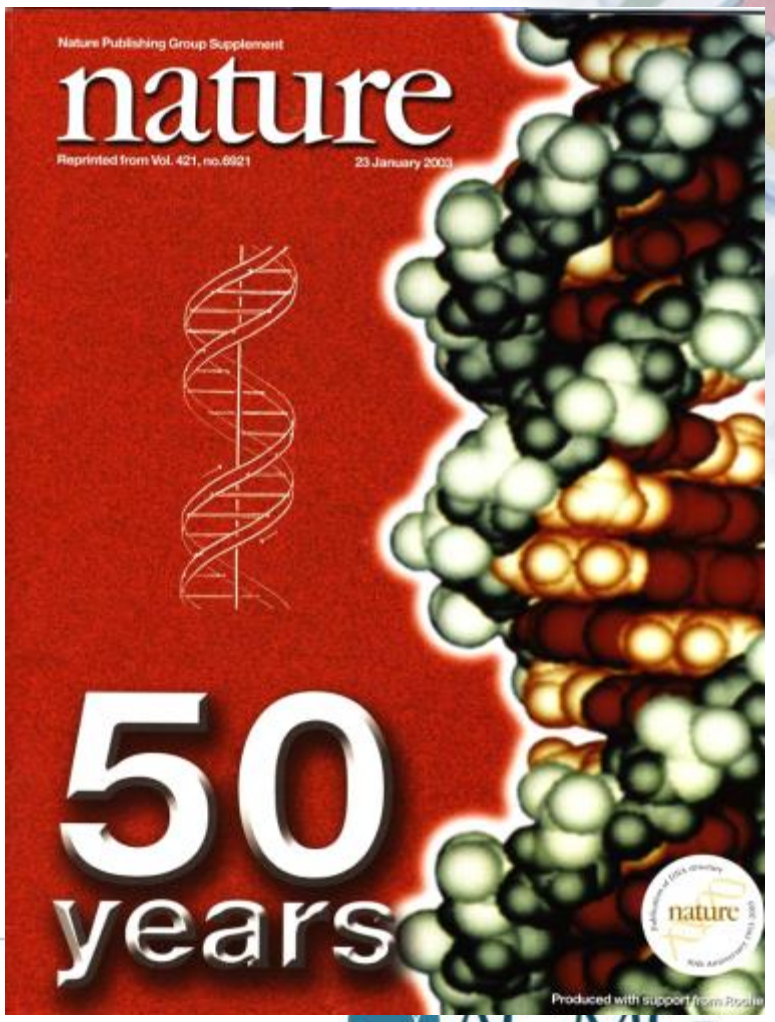
“DNA is Important!” OT Avery 1944





Thank you

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