The Next Generation of Genomic Testing: Billing and Reimbursement in the Genomic Era

Co-Moderators:

Jerry Feldman, MD, PhD, FACMG
Wayne State University School of Medicine
Detroit Medical Center University Laboratories

Cheryl Hess, MS, CGC
Detroit Medical Center University Laboratories
Why this session?…Why now?…Why ACMG?

• **WHY?** We all face billing/reimbursement issues regarding genetic testing
  – Laboratory
  – Clinical Geneticists
  – Genetic Counselors

• **WHY NOW?** Centers for Medicare and Medicaid Services (CMS) and commercial payers are determining rates of reimbursement for genetic and genomic tests that are impacting
  – Patient care and our ability to order tests
  – Ability to receive adequate reimbursement for tests performed

• **WHY ACMG?** ACMG is the advocate for and representative of providers of medical genetic/genomic services and their patients
  – These decisions will determine the future of this specialty
  – But each of us must also individually and collectively work together to achieve success
Session Objectives

• Recognize CMS language and its application to billing and reimbursement for genetic testing in the clinical laboratory

• Explain methods and resources used by CMS and commercial payers in determining reimbursement policies related to genetic and genomic tests

• Describe genetic and genomic test utilization management strategies that decrease medical spending and improve patient care

• Describe how ACMG is responding to these challenges to benefit patients and membership
Presentations and Schedule

• Introduction
  – Jerry Feldman MD, PhD

• Billing, Reimbursement and Coverage in Laboratory Genetics - The Evolving Story
  – Kay E. Jewell, MD

• Health Plan Perspectives on the Emergence of Molecular Medicine
  – Joanne Armstrong, MD

• Genetic Test Utilization Management - Benefits to the Laboratory, Physician, Payer and Patient
  – Cheryl Hess, MS, CGC

• ACMG's Voice in the National Dialogue on Billing and Reimbursement for Molecular Diagnostics
  – David Flannery, MD, FACMG, ACMG
Review of Billing, Coverage and Reimbursement in Laboratory Genetics

Kay E. Jewell, MD
March 26, 2015
Disclosure

• Consultant to Senergene LLC on clinical laboratory issues
Agenda

• How we got to where we are today with genetic/molecular diagnostic codes and problems with payment

• New Codes in 2015 – potential issues

• Changes coming starting 2015 from PAMA legislation

• Current issues with coverage and payment
What was needed to manage genetic/molecular diagnostic (dx) testing projections

• Revision of the coding system
• Evidence to support the medical use of the test in clinical management of patients
• Changes in reimbursement for tests
Need New Codes to Report Tests to Payers

- Old system, ‘stacking’ codes
  - Not obvious what was done, what was tested for and for what diagnosis.
  - Variability in what tests were performed to arrive at the same answer

- 3 labs could perform tests to assess \textit{KRAS solid tissue}

- Lab 1 – charges $273.76
- Lab 2 – charges $268.10
- Lab 3 – charges $304.08
## New AMA CPT Codes© – Implemented January 2013

<table>
<thead>
<tr>
<th></th>
<th>Tier 1</th>
<th>Tier 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test specific</strong></td>
<td>Majority of commonly performed, single analyte molecular tests</td>
<td>Lower volume. Arranged in 9 levels based on the technical and interpretive work performed</td>
</tr>
<tr>
<td><strong>Frequency, other characteristics</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Examples:</strong></td>
<td>APC, BRF, CFTR, FMR1</td>
<td>Level 1 – single variant</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Level 4 - sequence single exon</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Level 5 – sequence 2-5 exons</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Level 9 – sequence &gt;50 exons</td>
</tr>
<tr>
<td><strong>Payment</strong></td>
<td>Based on the work for the test described</td>
<td>Intention of code developers: To be uniform by Level because analytes/genes were grouped based on similar levels of work</td>
</tr>
</tbody>
</table>
Medicare – Decisions About New Codes

Decision #1– Should the codes be part of the physician or clinical lab fee schedule?

Decision #2 – What method should be used to set payment

• Option 1 – Crosswalk
  – Identify similar tests already assigned a code
  – Benchmark payment based on payment level for existing codes

• Option 2 - Gapfill
Gapfill Process

• Year 1
  – Labs submit data to their MAC: charges for the test, costs of resources and payment rates of other payers
  – April 30, 2013 - CMS posted interim contractor-specific amounts
  – 60-day comment period on interim amounts (May-June)
  – CMS posted 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

• Year 2 – CMS adopts national payment rates for the codes based on Year 1 results

• Challenge with this approach
  – Labs, especially small labs, did not submit data.
  – Costs of larger labs dominated the data collected and final payment rates.
2013 – Year of Non-Payment

- Blamed on gapfill process
- THE PROBLEM WAS NOT JUST THE GAPFILL PROCESS
Getting paid for a test/service is a 2-step process

1 – Coverage – is the test covered?

2 – Payment: if covered, how much do we pay?*

*If a test/service is not covered, the MAC is not required to set a payment.
The Problem Was Coverage

• All payers define what will be covered in their coverage policies
• The majority of decisions for Medicare are defined by the MAC (Medicare Administrative Contractor – they process the claims)
• Coverage decisions by MACs are called Local Coverage Determinations (LCDs)

• Most MACs did not have LCDs that addressed coverage for genetic/molecular dx testing
Two Questions in the Coverage Decision

1st question: Is the test excluded from being covered based on the statute/law (Medicare)?

– Is the test being done for a person who has no symptoms of the condition being tested?

– If the person is asymptomatic, it is considered ‘screening’ and is NOT covered by law.
Coverage Issue – ‘Statutory Exclusion’

• Testing for most inheritable conditions was declared ‘statutory exclusion’ = not covered
• The decisions were based on belief that
  – Testing was only performed to screen the asymptomatic persons or was being done to determine carrier status.
  – There is no clinical reason for the test or use of the results in older people.
• RELEVANCE TO PATIENTS & CLINICIANS:
  – Statutory exclusions cannot be appealed
• IMPACT ON SETTING PAYMENT LEVELS:
  – Testing for most inheritable conditions was excluded from coverage = ‘not covered’.
  – MACs are not required to set a reimbursement level for a code that is not covered.
Impact of ‘statutory exclusion’ status for a code/test & no payment level by Medicare

- Many payers use Medicare reimbursement levels to set their payment rates
  - Medicaid
  - Commercial payers

- Medicaid did not have payment rates to pay for testing
Coverage for Other Genes, e.g. cancer-related

2nd question: If not excluded, is the test ‘medically reasonable and necessary’ for the diagnosis or treatment of a symptomatic condition/problem for the beneficiary?

- Is the information used to diagnose a condition? How does it relate to other current methods of diagnosis?
- Is the information used in the management of the patient’s condition?
- What is the scientific evidence that supports the use of the results in management and outcomes?

- AKA – clinical utility
Palmetto MolDX Program

- 2012 – started as a pilot, now it officially sets coverage policy for 2 MAC regions

- Created its own ‘rules’
  - Created a ‘unique identifier’ requirement for each test
  - Requires submission of scientific evidence and approval to obtain payment
  - Technology Assessment: prove clinical validity & utility

- Creative use of CPT codes and coverage
  - Multiple tests (genes) tested on a specimen are declared to be a ‘panel’ and denied if 1 of the genes is not covered
  - Assigned FDA approved tests to NOC codes with different (higher) payment levels

- Published decisions about coverage as statements on website
  - Outside the LCD process
  - Not subject to clinician & public input or reconsideration
Where Are We With New Codes in 2015?

• Payment
  – Will be set by gapfill, same process as in 2013
  – MACS do not have to set a payment amount if the AMA CPT code© is not covered

• Coverage
  – Will depend on current LCDs and new LCDs
  – Critical issue with codes that require testing of multiple genes
    • Proving clinical use of the combination of genes in the diagnosis and management of patients
    • Coverage of testing performed ‘all at once’ versus the sequencing of tests based on the results of the previous test (reflex testing)
Coverage Issues for Code for Lynch Syndrome

- **CPT Code 81435**: Hereditary colon cancer syndromes (eg, Lynch syndrome, familial adenomatosis polyposis); must include analysis of at least 7 genes, including APC, CHEK2, MLH1, MSH2, MSH6, MUTYH, and PMS2
- **CPT Code 81436**: … must include analysis of at least 8 genes, including APC, MLH1, MSH2, MSH6, PMS2, EPCAM, CHEK2, and MUTYH

Issues to be addressed to decide coverage:
- Each gene listed has evidence of clinical utility
- All genes are indicated for the condition
- Evidence supports the need for all the genes for clinical management
- Testing all genes at once vs reflex testing
Changes Coming in 2015 and Beyond – PAMA*

- Creation of an Expert Advisory Panel by 7/1/2015
- Option for CMS to designate 1-4 MACs to establish coverage policy or establish coverage and process claims for all Laboratory Tests, including genetic/molecular dx testing
- Requires MACs to use the LCD process to establish coverage policies for lab tests, effective 1/1/2015
- Creates special rules for “Advanced Diagnostic Tests”
- Changes reimbursement

*PAMA – Protecting Access to Medicare Act 2014
2015 - Challenges for Coverage/Payment

• Statutory Exclusion of tests used for diagnosis in adults
  – Adopt coding approach used for lab tests to identify multiple
    indications (statutory exclusion, medical necessity, and diagnoses to be
    reviewed individually)
  – Need clinical evidence to describe clinical conditions and reasons for
    testing in adults
    • Examples: FMR1 testing for FXTAS, Cystic Fibrosis testing associated with drug
      selection, Proving the clinical utility of new genomic sequencing codes

• Clinical studies to support medical use of testing reported by new codes

• Submission of cost data to MACs for new AMA CPT codes© to ensure better payment levels

• Respond to rulemaking required to implement PAMA
Health plan perspectives on the emergence of molecular medicine

Joanne Armstrong, MD
March 26, 2015
Faculty Disclosures-None
Agenda

• Overview of healthcare landscape and emergence of genomic technologies
• Technology assessment (coverage) process
• Linkage of coverage to reimbursement
• Challenges/opportunities to expansion of genomic services
The Big Picture

Poor quality and misallocation of resources are well documented
- As many as 200,000 hospitalized patients die annually from preventable medical error
- Average compliance with preventive, acute or chronic care guidelines is 53%
- 30% ($700B annually) of all health care spending is waste; $70 billion on incorrectly prescribed drugs

3. The Healthcare Imperative: Lowering Cost and Improving Outcomes, IOM, 2011
Genetic Laboratory Test Market

US Market 2012

$15.5B (5.8% trend)

$7.8B (9% trend)
Laboratory Based Diagnostics: Cost Impact

Rapid increase in the availability and adoption of genetic tests\(^1\)

Costs are modest (<1% of total medical spending) but trends are steep\(^2\)
- 1/3 oncology, 1/3 reproductive, 1/3 other (ID, GI, cardiac)
- Annual trend 11% between 2008 – 2012

“Blockbuster” list pricing is emerging
- BRCA - $2,400
- HIV tropism - $2,000
- Cell free DNA - $2,700
- Gene expression profiling - $4,000

2. Aetna, 2013
Cost Impact of Next Generating Sequencing (NGS)

- The cost of sequencing one million DNA bases has dropped dramatically since 2008
  - 5 cents/Mb; $5,000/genome

- The total cost of testing should decrease
  - Examples are emerging (e.g. prenatal carrier screening)

- In many cases, aggregate costs have increased as dozens of tests/markers of unproven significance are added to test panels.
  - SNP Array/Autism panel -$15,000

Utility of the additional information often uncertain

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<tr>
<th>Postnatal High Density SNP Array &amp; Autism Spectrum Disorders / Intellectual Disabilities / Multiple Anomalies NGS Panel</th>
<th>8129 Postnatal High Density SNP Array</th>
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<td>81408 ASPM, CHD7, CNTNAP2</td>
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<tr>
<td>TOTAL</td>
<td></td>
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<td>$ 15,130.00</td>
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Emergence of Biologic Therapies

Rapid increase in availability of new biologic medications\(^1\)
Biologics represent 25\% of new drugs approved by FDA since 2001

Biologic therapy trend and cost are higher than traditional therapy\(^2\)

Kalydeco (ivacaftor) - $350,000 per treated individual per year
Solaris (eculizumab) - $409,500 per treated individual per year
Elaprase (idursulfase) - $525,000 per treated individual per year

\(^1\) CVS/Caremark Trend Forecast 12/14/2010
\(^2\) Based upon AWP costs and standard adult dosing
<table>
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<tr>
<th>Class</th>
<th>Drug</th>
<th>Companion Dx</th>
<th>Tx cost per year</th>
<th>Coverage</th>
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<tbody>
<tr>
<td>Oncology</td>
<td>Campath (alemtuzumab)</td>
<td>CD52</td>
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<td>Oncology</td>
<td>Erbitux (cetuximab)</td>
<td>KRAS</td>
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<td>Oncology</td>
<td>Gleevec (imatinib)</td>
<td>cKIT (CD117), BCR-ABL</td>
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<td>Oncology</td>
<td>Herceptin (trastuzumab)</td>
<td>Her-2</td>
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<td>Pulmonary</td>
<td>Kalydeco (ivacaftor)</td>
<td>G551D</td>
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<td>Oncology</td>
<td>Ontak (denileukin)</td>
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<td>Infectious Disease</td>
<td>Peginterferon</td>
<td>Hep C genotyping IL28B Polymorphism</td>
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<td>Cardiology</td>
<td>Plavix (clopidogrel)</td>
<td>CYP2C19</td>
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<td>Oncology</td>
<td>Rituxin (rituximab)</td>
<td>CD20</td>
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<td>Oncology</td>
<td>Sprycel (dasatinib)</td>
<td>BRC-ABL T315</td>
<td>$92,000</td>
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## Companion Diagnostics to Optimize Drug Therapy

<table>
<thead>
<tr>
<th>Class</th>
<th>Drug</th>
<th>Companion Dx</th>
<th>Tx cost per year</th>
<th>Coverage</th>
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</thead>
<tbody>
<tr>
<td>Neurology</td>
<td>Tegretol (carbamazepine)</td>
<td>HLA-B*1502</td>
<td>$700</td>
<td>Yes-Asian pop. only</td>
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<td>Oncology</td>
<td>Tarceva (erlotinib)</td>
<td>EGFR&lt; KRAS</td>
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<td>Oncology</td>
<td>Tasigna (nilotinib)</td>
<td>BCR-ABL T3151</td>
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<td>Oncology</td>
<td>Tykerb (lapatinib)</td>
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<td>Oncology</td>
<td>Vectibix (panitumumab)</td>
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<td>Oncology</td>
<td>Xalkori (crizotinib)</td>
<td>ALK fusion</td>
<td>$117,000</td>
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<td>Xenazine (tetrabenazine)</td>
<td>CYP2D6</td>
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<td>Oncology</td>
<td>Zelboraf (vemurafenib)</td>
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<td>Neurology</td>
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<td>Warfarin</td>
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## Companion Diagnostics and Biomarkers: Opportunities

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<th>Clinical Category</th>
<th>% Category Spend</th>
<th>Biomarker</th>
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<tbody>
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<td>Anti Inflammatory</td>
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<td>HUMIRA</td>
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<td>ENBREL</td>
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<td>REMICADE</td>
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<td>Transplant</td>
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<td>PROGRAF</td>
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<td>TACROLIMUS</td>
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<td>RAPAMUNE</td>
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<td>YERVOY</td>
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The Value Proposition

Will genetic/personalized medicine improve the quality, safety, and/or cost effectiveness of delivered health care?

or....

Will genetic/personalized medicine drive additional medical costs with marginal health care gains?
Health Insurance: How it Works

• Health insurance is a contract between an insurance provider and the purchaser (individual user or employer plan sponsor)
• The contract contains a “summary plan description” (SPD)
  o Principles that guide the benefit plan
  o Benefits covered
  o Services excluded
  o Eligibility requirements to use the benefits
• Plan sponsor funding arrangement considerations

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<tr>
<th>Funding Arrangement</th>
<th>Premium</th>
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<td>Yes</td>
<td>Employer Plan Sponsor</td>
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Aetna Coverage Policy Principles

- Services are related to prevention, diagnosis, or treatment of an illness
- Services must be medically necessary and not experimental and investigational
- Information will affect the course of treatment of the member
- Care and/or treatment is likely to improve outcome
- Improvement must be attainable outside investigational settings
- Services are consistent with plan design

...Same coverage policy principles for genetic technologies as for all other technologies.
Evidence Standards for Coverage

Covered services must have:

- Published, peer reviewed, scientific evidence that permits conclusions concerning test performance and the effect of the technology on health outcomes.
  
  - Analytic validity
  - Clinical validity
  - Clinical utility
- Final approval from the appropriate governmental regulatory bodies, when required
- Demonstrate improved net health outcome and be as beneficial as any established alternatives

...Same evidence standards for genetic technologies as for all other technologies.
Sources of Evidence for Clinical Policy Support

• Peer-reviewed medical literature referenced in PubMed database
• Evidence-based clinical practice guidelines in AHRQ’s National Guideline Clearinghouse database
• Practice guidelines of relevant professional colleges
• Technology assessments indexed in NLM’s Health Services/Technology Assessment Text (HSTAT) database
• Regulatory status of technology
• For oncology drugs, Aetna considers the indications with consensus of 2B or greater from the NCCN Drugs and Biologics Compendium
• Opinions of relevant experts may be solicited where necessary
Noninvasive Prenatal Testing for Fetal Aneuploidy

ABSTRACT: Noninvasive prenatal testing that uses cell free fetal DNA from the plasma of pregnant women offers tremendous potential as a screening tool for fetal aneuploidy. Cell free fetal DNA testing should be an informed patient choice after pretest counseling and should not be part of routine prenatal laboratory assessment. Cell free fetal DNA testing should not be offered to low-risk women or women with multiple gestations because it has not been sufficiently evaluated in these groups. A negative cell free fetal DNA test result does not ensure an unaffected pregnancy. A patient with a positive test result should be referred for genetic counseling and should be offered invasive prenatal diagnosis for confirmation of test results.

Box 1. Indications for Considering the Use of Cell Free Fetal DNA

- Maternal age 35 years or older at delivery
- Fetal ultrasonographic findings indicating an increased risk of aneuploidy
- History of a prior pregnancy with a trisomy
- Positive test result for aneuploidy, including first trimester, sequential, or integrated screen, or a quadruple screen
- Parental balanced robertsonian translocation with increased risk of fetal trisomy 13 or trisomy 21.

However, the ACMG statement differs by what it does not say. Other organizations recommend that obstetricians offer NIPS only to women at high risk of aneuploidy because published studies on the methodology have not focused on women at average risk. But ACMG makes no mention of offering these tests based on risk, implying that offering these tests to all women is appropriate.

“ACMG believes there is no reason to believe that the test will not have performance characteristics (detection rate, positive predictive value, and negative predictive value) that exceed those of currently available screening tests,” says ACMG statement senior author Anthony Gregg, MD, a B. L. Stainaker Professor, Chief of Maternal Fetal Medicine (MFM), and Director of Obstetrics at Shands Hospital in Gainesville, Florida.
Aetna Clinical Policy Unit

• 3 full time dedicated MDs/PhD conduct preliminary reviews/draft CPB
• Physician-only Clinical Policy Council reviews and modifies all CPB drafts
• More than 800 Clinical Policy Bulletins (CPBs) developed
  o Multiple technologies considered within a single CPB
  o CPB contain evidence review, review history, coding, literature references
• Each CPB is reviewed at least annually or sooner if significant data or other factor supports it
• CPB policies become effective on the date of publication
  o [www.Aetna.com](http://www.Aetna.com)
Clinical Policy Bulletin: Genetic Testing

Number: 0140

Policy

Aetna considers genetic testing medically necessary to establish a molecular diagnosis of an inheritable disease under the following guidelines: 

- The member displays clinical features, or is at direct risk of inheriting the mutation in question (or both); and
- The result of the test will directly impact the treatment being delivered to the member; and
- After history, physical examination, pedigree analysis, genetic counseling, and completion of concomitant medications, a definitive diagnosis remains uncertain, and one of the following diagnoses is suspected:

<table>
<thead>
<tr>
<th>Genetic Condition</th>
<th>Genetic Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achondroplasia (FGFR3)</td>
<td>Hereditary polyposis coli (APC)</td>
</tr>
<tr>
<td>Abetalipoproteinemia (LP)</td>
<td>Hereditary spastic paraplegia 3 (SPG3A)</td>
</tr>
<tr>
<td>Alpha-thalassemia/ß-thalassemia disease (HBA1/HBA2, alpha globin 1 and alpha globin 2)</td>
<td>and 4 (SPG4, SPAST)</td>
</tr>
<tr>
<td>Aplastic anemia (GATA1, SNRPN)</td>
<td>Huntington's disease (ITRT, HD)</td>
</tr>
<tr>
<td>Beta-thalassemia (ß-thalassemia) (HBB)</td>
<td>Huntington's disease (ITRT, HD)</td>
</tr>
<tr>
<td>Cerebral palsy (CP) (CHRNA7)</td>
<td>Hyperoxaluria type 1 (FGFR3)</td>
</tr>
<tr>
<td>Cerebral palsy (CP) (CHRNA7)</td>
<td>Hyperoxaluria type 2 (FGFR3)</td>
</tr>
<tr>
<td>Cerebral palsy (CP) (CHRNA7)</td>
<td>Jackson-Weiss syndrome (FGFR3)</td>
</tr>
<tr>
<td>Cerebral palsy (CP) (CHRNA7)</td>
<td>Joubert Syndrome (JUBT1)</td>
</tr>
<tr>
<td>Cerebral palsy (CP) (CHRNA7)</td>
<td>Kennedy disease (SMA)</td>
</tr>
<tr>
<td>Cerebral palsy (CP) (CHRNA7)</td>
<td>Leber hereditary optic neuropathy (LHON)</td>
</tr>
<tr>
<td>Cerebral palsy (CP) (CHRNA7)</td>
<td>Leigh Syndrome and NARP (neuropathic muscle weakness, ataxia, and retinal pigmentations)</td>
</tr>
<tr>
<td>Cerebral palsy (CP) (CHRNA7)</td>
<td>Long QT syndrome (see below)</td>
</tr>
<tr>
<td>Cerebral palsy (CP) (CHRNA7)</td>
<td>Limb-girdle muscular dystrophy (LGMD2A, LGMD2B) (PFN1, titin-related proteins)</td>
</tr>
<tr>
<td>Cerebral palsy (CP) (CHRNA7)</td>
<td>Malignant hyperthermia (RyR1)</td>
</tr>
<tr>
<td>Cerebral palsy (CP) (CHRNA7)</td>
<td>Maple syrup urine disease (branched-chain keto acid dehydrogenase complex)</td>
</tr>
<tr>
<td>Cerebral palsy (CP) (CHRNA7)</td>
<td>Marfan's syndrome (TGFBR1, TGFBR2)</td>
</tr>
<tr>
<td>Cerebral palsy (CP) (CHRNA7)</td>
<td>McLeod's disease (Medium chain acyl-CoA dehydrogenase deficiency (MCAD))</td>
</tr>
<tr>
<td>Cerebral palsy (CP) (CHRNA7)</td>
<td>Myotonic dystrophy (DMPK gene)</td>
</tr>
<tr>
<td>Cerebral palsy (CP) (CHRNA7)</td>
<td>Myotonic dystrophy (DMPK, ZNF9)</td>
</tr>
<tr>
<td>Cerebral palsy (CP) (CHRNA7)</td>
<td>Naxos disease, type A (SNIP21, spinocerebellar ataxia 1)</td>
</tr>
</tbody>
</table>

(see below)
Prioritizing Requests for New or Updated CPBs

- New evidence, guidelines, consensus statements, changes in regulatory status or other information that is material to the status of the medical technology
- Questions from external or internal groups regarding a medical technology
- The potential impact of the technology on Aetna and its members
Clinical Policy Bulletin Linkage to Reimbursement

- Aetna Clinical Policy Council Drafts the CPB
- Aetna’s Legal Department
  - (reviews against state or federal mandates, other legal considerations)
- Chief Medical Officer sign-off
- CPB undergoes coding in Aetna systems (coding edits applied)
- Coding is linked to Aetna contracts/reimbursement
- Management strategies may be applied (precertification, formulary edits)
What is the Role of Cost and Cost-Effectiveness in Coverage Decisions?

• Aetna reviews the comparative effectiveness of new medical technologies
• Cost-effectiveness is not a determinant of the coverage decisions
• Cost and cost effectiveness does influence process by which technologies are managed within plan
  o Precertification
  o Disease management
  o Pharmacy management-formularies, step therapy
  o Network selection
Challenges to the (Greater) Adoption of Genetic Medicine

Science limitations:

   Clinical validity, clinical utility, actionability
Paucity of specific clinical guidelines
Concerns about cost and cost effectiveness

Clinician and patient/consumer preparedness
Direct to consumer marketing concerns
CPT coding challenges
Privacy considerations
Physician Genetic Knowledge in Practice

- 94% New findings are changing clinical practice in my area of expertise
- 97% Increased familiarity of genetics would benefit my patients
- 39% I am familiar with recent genetic research affecting my patients
- 36% My current genetic knowledge is sufficient to answer my patients questions

Impact of Marketing on Genetic Testing

Direct to consumer marketing and physician detailing have driven demand for testing

- 244% increase in demand for BRCA following DTC campaign\(^1\)
- 10% increase in Aetna test request year over year 2004-present
- Marketing drives both medically appropriate and non evidence based testing

Lack of counseling compounds non evidence-based testing

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2. Aetna, 2014
## Range of associated tests ordered with BRCA test panels

<table>
<thead>
<tr>
<th>CPT</th>
<th>CPT Description</th>
<th>CPT2</th>
<th>CPT Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81292</td>
<td>MLH1 GENE FULL SEQ</td>
<td>81264</td>
<td>IGK REARRANGEABN CLONAL POP</td>
</tr>
<tr>
<td>81298</td>
<td>MSH6 GENE FULL SEQ</td>
<td>81261</td>
<td>IGH GENE REARRANGE AMP METH</td>
</tr>
<tr>
<td>81295</td>
<td>MSH2 GENE FULL SEQ</td>
<td>81209</td>
<td>BLM GENE</td>
</tr>
<tr>
<td>81201</td>
<td>APC GENE FULL SEQUENCE</td>
<td>81401</td>
<td>MOPATH PROCEDURE LEVEL 2</td>
</tr>
<tr>
<td>81404</td>
<td>MOPATH PROCEDURE LEVEL 5</td>
<td>81342</td>
<td>TRG GENE REARRANGEMENT ANAL</td>
</tr>
<tr>
<td>81235</td>
<td>EGFR GENE COM VARIANTS</td>
<td>81220</td>
<td>CFTR GENE COM VARIANTS</td>
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<tr>
<td>81321</td>
<td>PTEN GENE FULL SEQUENCE</td>
<td>81203</td>
<td>APC GENE DUP/DELET VARIANTS</td>
</tr>
<tr>
<td>81275</td>
<td>KRAS GENE</td>
<td>81301</td>
<td>MICROSATELLITE INSTABILITY</td>
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<td>81210</td>
<td>BRAF GENE</td>
<td>81228</td>
<td>CYTOGEN MICRARRAY COPY NMBR</td>
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<td>81408</td>
<td>MOPATH PROCEDURE LEVEL 9</td>
<td>81407</td>
<td>MOPATH PROCEDURE LEVEL 8</td>
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<td>81310</td>
<td>NPM1 GENE</td>
<td>81323</td>
<td>PTEN GENE DUP/DELET VARIANTS</td>
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<td>81294</td>
<td>MLH1 GENE DUP/DELETE VARIANTS</td>
<td>81243</td>
<td>FMR1 GENE DETECTION</td>
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<td>81317</td>
<td>PMS2 GENE FULL SEQ ANALYSIS</td>
<td>81255</td>
<td>HEXA GENE</td>
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<td>81403</td>
<td>MOPATH PROCEDURE LEVEL 4</td>
<td>81251</td>
<td>GBA GENE</td>
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<td>81270</td>
<td>JAK2 GENE</td>
<td>81299</td>
<td>MSH6 GENE KNOWN VARIANTS</td>
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<tr>
<td>81315</td>
<td>PML/RARALPHA COM BREAKPOINTS</td>
<td>81400</td>
<td>MOPATH PROCEDURE LEVEL 1</td>
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<tr>
<td>81245</td>
<td>FLT3 GENE</td>
<td>81200</td>
<td>ASPA GENE</td>
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<td>81206</td>
<td>BCR/ABL1 GENE MAJOR BP</td>
<td>81330</td>
<td>SMPD1 GENE COMMON VARIANTS</td>
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<td>81297</td>
<td>MSH2 GENE DUP/DELETE VARIANTS</td>
<td>81240</td>
<td>F2 GENE</td>
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<td>81242</td>
<td>FANCC GENE</td>
<td>81207</td>
<td>BCR/ABL1 GENE MINOR BP</td>
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<td>81405</td>
<td>MOPATH PROCEDURE LEVEL 6</td>
<td>81208</td>
<td>BCR/ABL1 GENE OTHER BP</td>
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<td>81406</td>
<td>MOPATH PROCEDURE LEVEL 7</td>
<td>81205</td>
<td>BCKDHB GENE</td>
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<td>81479</td>
<td>UNLISTED MOLECULAR PATHOLOGY</td>
<td>81260</td>
<td>IKBKAP GENE</td>
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<tr>
<td>81300</td>
<td>MSH6 GENE DUP/DELETE VARIANTS</td>
<td>81290</td>
<td>MCOLN1 GENE</td>
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<tr>
<td>81319</td>
<td>PMS2 GENE DUP/DELET VARIANTS</td>
<td>81250</td>
<td>G6PC GENE</td>
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<tr>
<td>81402</td>
<td>MOPATH PROCEDURE LEVEL 3</td>
<td>81291</td>
<td>MTHFR GENE</td>
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<tr>
<td>81202</td>
<td>APC GENE KNOWN FAM VARIANTS</td>
<td>81241</td>
<td>F5 GENE</td>
</tr>
</tbody>
</table>

Aetna Internal Data, 2015
Summary

• New science and technology platforms are enabling a large increase in the number of available genetic tests.
  o Many have led to breakthroughs in clinical care
  o …but much of the information is unproven

• In order to realize the full potential of genomics on health and healthcare, we need to ensure the science is validated, clinical utility is demonstrated, and physicians and patients are supported to use them effectively.
Genetic Test Utilization Management

Benefits to the Laboratory, Physician, Payor and Patient

Cheryl Hess, MS, CGC
Detroit Medical Center University Laboratories
Utilization Management (UM)

- UM policies are trending in all areas of medicine
- Laboratory UM has been a focus of conscientious institutions for the last 5 decades
- Renewed or new focus in response to the changing billing and reimbursement policies
- Genetic (molecular) testing is an obvious early target
  - Increase in molecular test requests from all medical specialties
  - Relatively expensive; often referenced out

¹United Health Care, March 2012
Laboratory UM Goals

• Enhance patient care
  – Right test, right patient, right time
  – Identify duplicate or incorrect test orders

• Guide appropriate use of healthcare dollars
  – Avoid unnecessary charges
  – Maximize reimbursement
Genetic Test UM Value

- Initial publications from large reference labs
- 21 month retrospective review†
  - 7 genetic counselors reviewed molecular orders
  - Averaged 99 test changes/month
    - 26% of total requests for complex, germline molecular testing
    - Referring institutions were afforded an average collective savings of $48,000/month

†Am J Med Genet; 2014, vol 169A
Genetic Test UM Value

• 8 month review at an academic hospital laboratory†
  – Pre-determined criteria for review:
    • Individual tests that cost >$1000
    • Multiple genetic tests on the same requisition
    • Orders at non-preferred/International laboratories
    • Send-out requests for in-house assays
  – 251 test orders met criteria
    • 199/251 were genetic test requests
  – 76% (152/199) of genetic test orders approved
  – 24% (47/199) of genetic test orders were modified
    • 21 changed to sequential orders; 26 cancelled
  – Total Savings = $118,952 ($463/test)

†Arch Pathol Lab Med. 2014; 138: 110-113
Genetic Test UM Value

• 21 month period (4/2013-12/2014)

• 847 “genetic tests” reviewed
  – 644 (76%) were not modified in any way
  – 203 (24%) were changed/canceled
    • Tiered approach (36)
    • Changed to a ‘better’ test (24)
      – Limited → Comprehensive (8)
    • Changed reference lab (65)
      – 13/65 able to be performed in-house
    • Cancelled (56)

• Total savings of $226,632.40

†Detroit Medical Center University Laboratories, unpublished
UM Benefits Beyond the Bottom Line

• Hand written order: “NOD2 mutations”
  – Test reviewed due to patient’s in-house status
  – Script translated into LIS order for a proprietary prognostic assay for Crohn’s disease
    • Evaluates 3 snps in NOD2/CARD15
  – Contact with the clinician revealed the patient was being evaluated for Blau syndrome
  – Changed order to NOD2 sequencing at a different reference laboratory
UM Benefits Beyond the Bottom Line

• Electronic order for HBB sequencing
  – Patient had normal hemoglobin evaluation
  – Contact with clinician revealed:
    • History of persistent microcytic anemia
    • Previously negative alpha-thalassemia testing (common deletions)
    • Working diagnosis of delta-beta thalassemia
  – Discussed limitations of testing, as ordered
    • HBB sequencing unable to detect large deletions in beta globin gene cluster
  – Referenced the sample to a laboratory that could perform MLPA, as well alpha globin gene sequencing
The Hospital UM Process

• Is collaborative...
  – Lab Directors, Clinicians, Hospital Administrators
  – Genetic Counselors, Medical Assistants, Billing/Claims Staff
  – Medical Technologists, Lab Processing/Client Service Representatives, Phlebotomists
  – IT specialists

• But an influential leader is required
  – Consistent point of contact and support
    • For the UM policy development team
    • For providers and patients impacted by policies
UM Program Development

• Invite interdisciplinary team members
• Review current laboratory procedures
• Identify and prioritize goals
• Establish metrics for success
• Determine method(s) of implementation
• Document outcomes
• Educate and motivate!
Possible UM Goals

• Limit genetic test orders on inpatients
  – Timing of sample collection dictates billing/reimbursement
  – Test results often not available prior to discharge

• Develop clinical testing algorithms
  – Published guidelines and in-house expert consensus
  – Encourage cascade testing
    • Consider a DNA ‘extract and hold’ policy

• Optimize reference laboratory relationships
  – Establish quality metrics
  – Prioritize value of other services
  – Explore varied billing arrangements
Laboratory UM Benefits...

- **Patients**
  - Reduction in order entry errors
  - Equitable care in line with recommended algorithms

- **Clinicians**
  - Rely upon laboratory consultants to understand and maintain accurate information regarding esoteric test offerings

- **Payors**
  - Personnel and financial resources remain focused on medically appropriate test requests

- **Institutional Laboratories**
  - Understand the needs of their clinicians
  - Avoid unnecessary cost; Maximize reimbursement
For More Information

• Clinica Chimica Acta, Jan 2014, vol 427
  – 21 distinct papers on all aspects of laboratory UM

• National Society of Genetic Counselors
  – Industry SIG/Test Utilization Sub-committee
ACMG’s Voice in the National Dialogue on Billing and Reimbursement for Molecular Diagnostics

David Flannery, MD, FFACMG
Medical Director
American College of Medical Genetics and Genomics
• None
Objectives

• After this talk you will know and understand:
  • Who
  • What
  • Where
  • When
  • Why
  • How ACMG Advocates Regarding Access, Coverage and Reimbursement for Genetic Services
There’s a Genomic Revolution Going On in Medicine

That's Great, But Who Pays?

Jun 20, 2014

While sequencing the exomes of patients with rare diseases may end their diagnostic odysseys and possibly offer treatment ideas, insurers are beginning to re-think reimbursing such tests, Reuters reports. Insurance companies argue that there is no proof that sequencing results will lead to "meaningful treatments," the news agency adds.

"There are some companies that are saying out and out, we won't cover this test," says Christine Eng, the director of the Whole Genome Sequencing Laboratory at Baylor College of Medicine. Initially, she notes, more companies covered such testing, but the number of denials has increased as testing volume has increased.

"There's a lot of testing we're doing that's getting denied. We appeal it," adds Allen Bale, director of the DNA Diagnostic Lab at the Yale School of Medicine. "A lot of time that works, but it's case by case."

Sequencing, Asta's James Cross says, has gotten ahead of itself. His company, Reuters notes, makes coverage decisions based on whether an individual test

Breaking News

- Genomic Health Q4 Revenues Increase 3 Percent
- Hugh Kaul Foundation Gifts $7M for UAB Personalized Medicine Institute
- Rhoenix Gets $1.5M NIH Grant to Commercialize POC HIV/AIDS Test
- NIH Awards Maverick $150K STTR Grant
- Biocept Prices Public Offering of Stock and Warrants, Expects $10M in Proceeds
- WiseBio Inks Exclusive Licensing Deal with Renovar for Kidney Biomarkers
Our Guiding Principles in Advocacy:

We want to ensure that:

- Patients will have appropriate access to genetic tests available to diagnose and manage the condition associated with their signs and symptoms or their genetic risk.
- Physicians/clinicians will be able to order genetic tests that are medically indicated for their patients.
- Laboratories performing these genetic tests will be paid for said tests.
- The processes by which coverage and payment decisions are made are transparent and consistent with existing rules and regulations.
- Patients with genetic disorders will have access to clinical trials, which are promoted by clinicaltrials.gov, and which typically require that patients have genetic test results which confirm and characterize their disorder.
Please Note

• We cannot **lobby** to Congress or governmental agencies
  
  – ACMG is a not-for-profit organization and there are IRS rules
  
  – Also ACMG has several federal grants and this restricts us as well

• But, ACMG can **inform** and **educate** governmental officials
How Do We Advocate?

• Providing testimony at governmental hearings and workshops

• Submitting written comments to governmental hearings and workshops

• Publishing position statements in medical journals

• Publishing laboratory and medical practice guidelines

• Communicating our positions and policies through social media

• Participating with other stakeholder professional organizations ("The House of Medicine")
To Whom Have We Advocated?

- Payers
  - Medicare
  - Medicaid
  - Private Payers
  - Other

- Legislators
  - House Committee on Commerce and Energy
    » Health Sub-Committee
    » 21st Century Cures

- Regulators
  - FDA
Medicare

- Medicare is the largest payer in the US
- Nation-wide, but has regional MAC’s and LCD’s
- Dr. Jewell has explained the MolDX situation
Why Does Medicare Matter to Geneticists?

• True, there are some genetics patients who are covered by Medicare (and there will be more patients as time rolls on)

• But the real reason is that many other payers look to Medicare coverage policy and Medicare payment as a point of reference for their coverage and payment decisions
What Have We Advocated With Medicare About In This Past Year?

• 2015 Clinical Lab Fee Schedule

• Local Coverage Decisions in 2 MAC Regions
  – CGS (CT, IL, MA, ME, MN, NH, NY, VT)
  – NGS (IN, KY, MI, OH, WI)

▪ PAMA
Medicaid

- Medicaid is a State program
- We know that there are serious problems with State Medicaid programs’ coverage policies regarding genetic testing
- Our coalition of stakeholders was unable to convince CMS to develop policy centrally
  - Advocating with State Medicaid programs must happen at the local level (*This means You!*)
  - We are working on developing “dossiers” for each Tier 1 and Tier 2 Molecular Diagnostic CPT code, as tools to educate State Medicaid program policy decision makers
    - We need help with this work – contact the Economics Committee Chair, Sheila Dobins, or me
Providing Input into Private Payers’ Coverage Policy

December 3, 2014

Anthem, Inc.
Medical Policy Questionnaire

Policy Number: [Redacted]
Policy Title: Genetic Testing for [Redacted]

This questionnaire and draft policy, as part of the clinical vetting process for Anthem, are Confidential and Proprietary, for use only by the organization that sent these documents and its physician members or physician faculty. Its contents should not be disclosed to any other parties without advance written consent of Anthem.

Anthem, Inc. collects input from physicians practicing in relevant clinical areas on behalf of a national healthcare association ("Association") to support their processes for developing and maintaining medical policies.

We are currently reviewing the topic of Genetic Testing for [Redacted]. We are requesting your expert opinion regarding this topic and have developed a series of relevant questions presented in the table below.

The draft policy indicates genetic testing for [Redacted] is considered investigational. We are interested in your comments on the draft policy position, in particular, your input on genetic testing for specific [Redacted].

We have designed our process to help you avoid duplication of effort in reviewing various entities’ medical policies, with the goal of reducing your administrative burden. Your feedback and the feedback we receive from others on this topic will be shared with non-Anthem entities, including the Association.
Food and Drug Administration (FDA)

- Draft Guidance on proposed regulation of Laboratory Developed Tests (LDT’s)
  - We submitted extensive written comments to FDA
  - We participated on a Panel providing input to FDA at their Workshop on January 8 - 9 2015

- Public Workshop - Optimizing FDA’s Regulatory Oversight of Next Generation Sequencing Diagnostic Tests Public Workshop, February 20, 2015
  - We are submitting written comments
  - We will be making a 4 minute verbal public comment at the Workshop providing a summary of our recommendations
Other Avenues of Advocacy

- Position Statements, Commentaries published in medical journals
  - e.g. Evans and Watson Viewpoint commentary in JAMA Jan 5, 2015 re LDT’s

- AMA
  - House of Delegates
  - CPT
  - RUC

- Social Media
House of Delegates

• “The House of Delegates is the AMA’s policy-making body, and is the foundation of organized medicine in America. It is a democratic forum that represents the views and interests of a diverse group of member physicians and medical students who come together to establish broad policy on health, medical, professional and governance matters, as well as the broad principles within which AMA’s business activities are conducted. “

• ACMG is a member of the HOD because it is a medical specialty society and because a significant % of it MD members are AMA members

• ACMG has 1 HOD Delegate, Dr. Rod Howell

• And 1 Alternate Delegate, Dr. Reed Pyeritz,
AMA’s CPT Advisory Committee

- Provides input to the CPT Editorial Panel’s process for developing new CPT codes

  - ACMG’s current CPT Advisory Committee representative is:

- Additionally, Patrick Koty, now the former Chair of the ACMG Economics Committee, serves on the MoPath Workgroup and the MPAG which review and provide input to CPT in the development of molecular diagnostic CPT codes
ACMG’s Social Media Presence

• ACMG’s Twitter account
Help ACMG in Advocacy

• **Join** the Economics of Genetic Services Listserv
  – Join by sending e-mail to dflannery@acmg.net

• **Follow** ACMG’s Advocacy at the Advocacy tab on the ACMG.net home page, where you can read the documents ACMG has submitted to Congress, CMS, and the FDA

• **Volunteer** to help write gene dossiers for our armamentarium for responding to Medicare and Medicaid coverage policy proposals

• **Follow** ACMG on Twitter and retweet ACMG posts

• **Let** us know if you are on a payer medical advisory board/committee

• If you win the lottery, consider donating a large part of it to the ACMG Foundation to support expanding our resources for advocacy activities
ACMG Applauds Investment in Precision/Personalized Medicine

President Obama rolled out a plan on Jan. 30, 2015 to invest $215 million in "precision medicine". ACMG applauds this investment in genomic medicine and we look forward to providing input into the process moving forward as leaders in advancing the field of genetics and genomics into all of healthcare. President Obama said that precision or personalized medicine “gives us one of the greatest opportunities for new medical breakthroughs that we have ever seen.” ACMG is already actively developing the standards by which genomic medicine will be practiced including practice guidelines for laboratories and clinicians and is...
We Know, It’s a “Perfect Storm” Out There

- But, to quote Jack Welch:
  - “Control your own destiny or someone else will.”

- And to quote Helen Keller:
  - “Alone we can do so little; together we can do so much.”