Implementing a Genetic Testing Strategy: A Care Management and Payer Perspective

Presented by:
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HealthPartners
Minneapolis, MN
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Objectives

• Describe the rationale for establishing a genetic testing utilization program.
• Describe the role of a laboratory genetic counselor as it relates to physician orders for genetic testing
• Discuss the benefits of a genetic testing formulary for the healthcare system and for payer organizations
• List two measurable results than can be achieved through a genetic testing utilization management strategy
HealthPartners

- Founded in 1957 as a cooperative (Group Health)
- Integrated health care organization providing health care services and health plan financing/administration
- Single, separate employer legal structure
- Largest consumer-governed nonprofit health care organization in the nation
- Serves more than 1.5M medical/dental health plan members
- Includes a multispecialty group practice of more than 1,700 physicians
- More than 22,500 employees
### HealthPartners – Laboratory System

- **Hospitals**
  - Regions Hospital – St. Paul, MN
    - Centralized microbiology and toxicology laboratory for system
  - Methodist Hospital – St. Louis Park, MN
  - Lakeview Hospital – Stillwater, MN
  - 3 critical access hospitals – Western, WI
    - Hudson Hospital
    - Westfields Hospital
    - Amery Hospital
- **Central Independent Laboratory**

### HealthPartners – Clinic Laboratories (specialty and primary care)

- Park Nicollet Clinics – 22 locations
- HealthPartners Medical Group – 39 locations
- Central Minnesota Clinic
- Clinics associated with critical access hospitals – 7 locations
- One integrated pathology group – employed in specialty practice (25 pathologists)
- Well @ Work Clinics – 12 locations
- Retail Clinics (Coburns grocery stores – 2 locations)
- Virtuwell – online clinic
Genetic Test Optimization Utilization

Scope of genetic testing

- ECRI update on current stats related to GT:
  - According to Genetests.org*:
    - 53,071 tests available worldwide
    - For 4,375 disorders
    - Involving 5,184 genes
    - Offered by 655 labs

*Source: www.genetests.org July 5, 2015
Median Household Income

MN $59,836

WI $52,413

Housing
Utility bills

Transportation

Food 90%

Personal insurance
Healthcare

Childcare
Credit cards
Autism Spectrum Disorder

- SNP (Single Nucleotide Polymorphism) array
  $1,286

- Syndromic Autism Panel
  $5,500

- 12% of annual income

Pause for the Cause

- Genetic testing may result in significant financial damage to patients

- Genetic testing may result in undue harm to patients

- Informed consent and the GT Lab mitigates harm
UM – Different Approaches

Gentle
- Posting of guidelines on the requisition
- Computerized reminders regarding utilization guidelines

Medium
- Utilization report cards
- Changes to manual requisition

Strong
- Privileging
- Lab test formulary
- Utilization report card with peer or leadership review
- Requirement for high-level approval (e.g., Pathologist) or consultation (e.g., genetic counselor)

Gentle Guidance → Strong Guidance


Proposed GT Operations & Stakeholder Organizations

GT Steering Committee
Meets Bi-Monthly

P & T Committee
Medical Director Committee

GT Formulary Committee
Meets quarterly

GT Advisory Groups
Meets annually and ad-hoc

GT Leads
Meets weekly

GT Health Plan Operations Workgroup
GT Care Group Operations Workgroup

GT Stakeholders
Questions we consider when reviewing tests

- Is the test appropriate, and is it the optimal test for this particular patient?
  - methodology, testing lab, quality metrics, cost, coverage
- Does the test have clinical utility?
- Can sequential ( tiered) testing be considered?
- Are there alternate, non-genetic tests that are more appropriate?
- Is this the best person in the family to test?
- What is the cost of the test?
- Will the patient’s insurance cover the cost?
The value of genetic test UM

• Provide the right genetic test to the right patient at the right time, through evidence-based decision support tools
• Improve affordability for our patients, institution, and health plan
• Increase patient satisfaction
• Improve patient care and avoid harm to the patient – e.g., financial damage, misdiagnosis or delayed diagnosis, incorrect treatment, incorrect interpretation of results

Laboratory-based genetic counselors

• Spring 2015: Approval to hire two full-time laboratory based genetic counselors
• Two candidates – recent graduates from University of Minnesota – started in June 2015
• One based at Regions Hospital – supports Regions, Lakeview and Wisconsin critical access hospitals and HealthPartners Clinics
• One based at Methodist Hospital and supports hospital and Park Nicollet Clinics
• Work collaboratively and provide cross coverage
Overview of our genetic test utilization management (UM) programming

- **All** built/misc. send-out genetic tests ordered by a non-genetics professional are reviewed, regardless of cost
- High volume, low cost tests are typically ordered by family/internal medicine or a subset of specialists
  - e.g., hereditary hemochromatosis, alpha-1 antitrypsin deficiency
- Gene panels are ordered by specialists, especially neurology, cardiology, pulmonology, allergy & asthma, genetics
- For **appropriately ordered genetic tests**, the provider requested assistance from the genetic counselor **before** ordering in approximately 30% of cases
Genetic testing referral order in Epic (REF810) – Step 2

- REF810 order goes to laboratory genetic counselor (GC) InBasket, GC reviews order
- Patient After Visit Summary (AVS) states that GC is reviewing order, patient does not go directly to lab

Genetic testing referral order in Epic (REF810) – Step 3

- GC may contact care team with questions
- After shared decision making between GC, provider, and patient, if testing is indicated the GC can place a pending test order (next slide)
- Provider authorizes order and care team contacts patient to make lab appointment
Genetic testing referral order in Epic (REF810) – Step 3 (cont’d)

Tracking genetic test UM metrics

- Microsoft Access database
Examples of test mis-ordering

- Duplicate tests; most tests are “once in a lifetime”
- Requesting hereditary hemochromatosis test before assessing ferritin level
- No longer sending out MTHFR genotyping due to lack of clinical utility (ACMG recommendations)
- Cystic fibrosis screening panel versus sweat test
- Full gene sequencing when a mutation is known in the family (order targeted analysis)

Examples of test mis-ordering (cont’d)

- Tiered approach - order gene(s) with highest yield first, then reflex to larger gene panel
- Testing an unaffected family member when an affected individual is available for testing
- Misconception that only one lab offers a test (example: neurology tests from Athena)
- In some cases, referral to a genetics professional is strongly recommended rather than ordering a test
Interactions with providers

- Laboratory GCs are not “gatekeepers” to testing
- Majority of interactions have been positive, providers are appreciative of recommendations and assistance with ordering genetic tests
- Several providers have placed a REF810 referral order more than once after seeing benefits of reaching out to laboratory GC before placing test order
- Cannot catch everything or convince every provider but focus on the “wins”

Other projects involving our laboratory GCs

- Collaboration opportunities for laboratory and clinical GCs
- Informed consent requirement (reference lab)
- MTHFR and hereditary hemochromatosis test alerts in EHR
- Universal Lynch syndrome screening for colon and endometrial cancers
- Expanded cystic fibrosis screening panel
- Non-invasive prenatal testing (NIPT) testing lab selection
- Collaboration with HealthPartners Plan - Advisory groups that help to inform coverage policies
- Genetic testing formulary (next slide)
### Lab GT Formulary for Care Group Use

<table>
<thead>
<tr>
<th>Test</th>
<th>Guidance/Indication</th>
<th>Laboratory/Unit Code</th>
<th>IF Volume</th>
<th>P/B Volume</th>
<th>Specialty</th>
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### Raw data from UM program graph, June 2015-May 2016

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<th>Sept-Nov '15</th>
<th>Dec '15-Feb '16</th>
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Cost savings = $263,400
Data from HealthPartners/Park Nicollet UM program, June 2015-May 2016

UM Solutions Over Time - June 2015 to May 2016 (n=904 cases)

Cost savings = $263,400 (Through 12 months - $295,000)

DATA is on the next slide

Lab Genetic Counselors
2016 Metrics/Report Card

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<th>Metric</th>
<th>Jan 2016</th>
<th>Feb 2016</th>
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<tr>
<td>Industry Benchmark = 30% Order Modify/Cancel</td>
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<td>Avg: $400 per case savings</td>
<td>$279</td>
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<td>GT Lab Formulary Implementation</td>
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GT Steering Committee Meeting 3/31/16

Savings July 2015 to present:
Jan $133K
Feb $176K
Mar $195K
Data from HealthPartners/Park Nicollet UM program, June 2015-May 2016

- Orders for hereditary hemochromatosis = 25% of total cases reviewed (n=904)
- Orders by genetics professionals that are reviewed = 5% total cases; almost all are approved
- Orders that were pre-reviewed by GCs = almost 17% last quarter
  - Pre-reviewed means the GCs were consulted before the provider ordered the test; consults via email, phone, InBasket, REF810
- “Pre-reviewed” trending up, “modify/cancel” trending down
- “Approved” tests tend to be high volume, low cost; “modified/cancelled” tests tend to be low volume, high cost

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### Genetic Testing Advisory Groups

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<th>Advisory Group Name</th>
<th>Conclusions / Learnings</th>
<th>Action(s)</th>
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</table>
| Molecular Profiling (Gene Expression) Profiling | - Genetic counseling is not relevant to molecular profiling assays  
- No clinical utility in repeat testing  
- Coverage of lung cancer molecular profiling panels should be reevaluated in future. | - Coverage policy name revised to incorporate "molecular profiling" instead of "gene expression profiling"  
- Reference to genetic counseling removed  
- Coverage position on assays remains unchanged |
| Developmental Delay & Autism Spectrum Disorder (ASD) | - Recommendation for stepped approach to testing  
- First-tier tests are array with limited genotype  
- Second-tier tests are single-gene analysis, multi-gene panels, and whole exome sequencing  
- Only genetics or developmental pediatricians should order second-tier tests | - Coverage policy created with stepped approach  
- No Coverage for multi-gene panels due to lack of reliable evidence |
| Pharmacogenetics | - No clinical value for CYPI450 for Flavix, MTHFR, and S-Hit toxicity assays  
- Little clinical value for behavioral health medications  
- UGT1A1 assays do have indications for use | - Coverage policy updated to include coverage for UGT1A1 assays for patient with hyperbilirubinemia prior to initiation of phenacemide therapy  
- Other coverage positions remain unchanged |
## Genetic Testing Advisory Groups

<table>
<thead>
<tr>
<th>Advisory Group Name</th>
<th>Conclusions / Learnings</th>
<th>Action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurology</td>
<td>In development:</td>
<td>-Moving neuromuscular (ataxia and Charcot Marie Tooth) to a later round</td>
</tr>
<tr>
<td></td>
<td>-Scope:</td>
<td>-Schedule and facilitate meetings in April/May timeframe</td>
</tr>
<tr>
<td></td>
<td>* Pediatric: inherited forms of epilepsy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Adult: inherited forms of dementia</td>
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<tr>
<td></td>
<td>-Membership</td>
<td></td>
</tr>
<tr>
<td>NIPT / Reproductive</td>
<td>In development:</td>
<td>-Schedule and facilitate meetings in April/May timeframe</td>
</tr>
<tr>
<td></td>
<td>-Scope:</td>
<td>-Schedule and facilitate meetings in April/May timeframe</td>
</tr>
<tr>
<td></td>
<td>* NIPt and carrier screening, e.g. CF</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Membership includes Obstetrics, Perinatology, Prenatal Genetic Counselors</td>
<td></td>
</tr>
<tr>
<td>Cardiology</td>
<td>In development:</td>
<td>-Schedule and facilitate meetings in April/May timeframe</td>
</tr>
<tr>
<td></td>
<td>-Scope:</td>
<td>-Schedule and facilitate meetings in April/May timeframe</td>
</tr>
<tr>
<td></td>
<td>* arrhythmias, cardiomyopathies, genetic cardiovascular risk assessments, and connective tissue disorders</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Membership includes Cardiology, Genetics, Cardiology Genetic Counselors</td>
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</tbody>
</table>

### Proposed Membership for Genetic Testing Advisory Round 2

<table>
<thead>
<tr>
<th>ROUND 2</th>
<th>Neurology</th>
<th>NIPT / Reproductive</th>
<th>Cardiology</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Staff Support</strong></td>
<td>Gemma Edgar, MS, CGC</td>
<td>Shellie Kiele, PhD, MS, CGC</td>
<td>Angela Easter, BSN, RN</td>
</tr>
<tr>
<td><strong>Adult Neurology</strong></td>
<td>Michael Rosenbaum, MD (HPMG)</td>
<td>John Haring, MD (HPMG)</td>
<td>Danish Ravi, MD (HPMG)</td>
</tr>
<tr>
<td></td>
<td>Martha Nance, MD (Park)</td>
<td>Joan Kreider, MD (HPMG)</td>
<td>Bill Nelson, MD (HPMG)</td>
</tr>
<tr>
<td></td>
<td>Teresa Tran Lim, MD (Park)</td>
<td>Katie Krumwiede, MD (HPMG)</td>
<td>David Homans, MD (Park)</td>
</tr>
<tr>
<td><strong>Pediatric Neurology</strong></td>
<td>Peter Karchewski, MD (U of MN)</td>
<td>Diana Damilano, MD (Park)</td>
<td>Thomas Kottke, MD (HPMG)</td>
</tr>
<tr>
<td></td>
<td>Gerald Raymond, MD (U of MN)</td>
<td>Lisa Pratt, MD (Park)</td>
<td>Marni Kaluzinski, MD (Park)</td>
</tr>
<tr>
<td></td>
<td><strong>Adult Neurology CGC</strong></td>
<td>Thomas McVey, MD (Park)</td>
<td>Katie Mancenido, MD (HPMG)</td>
</tr>
<tr>
<td></td>
<td>Matt Bauer, MS, CGC (U of MN)</td>
<td>prenatal GC’s</td>
<td><strong>Cardiology</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Pediatric Neurology CGC</strong></td>
<td>Katie Baker-Lange, MS, CGC (Park)</td>
<td>Deb Johnson, MD (HPMG)</td>
</tr>
<tr>
<td></td>
<td>Chelsea Alexander, MS, CGC (Gillette)</td>
<td>Jessica Greenberg, MS, CGC, (UM-Fairview)</td>
<td>Mary Eva Pianterra, MD (Pediatric Genetics, U of MN)</td>
</tr>
<tr>
<td></td>
<td>Maria Johnson, MS, CGC (U of MN)</td>
<td>Marie Rumon-Kennelly, MS, CGC (HCMC)</td>
<td><strong>Genetics</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Genetics</strong></td>
<td>New Hire, MS, CGC (Park)</td>
<td>Sarah Mata, MS, CGC (Mayo)</td>
</tr>
<tr>
<td></td>
<td>Deb Johnson, MD (HPMG)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Vendor RFP

- Vendor candidates:
  - NextGxDx, Inc.
  - eviCore Healthcare
  - McKesson (on-hold due to highest cost and dependency on use of Z codes).
- Both NextGxDx and eviCore have received 2 years of HP claims data trend analysis
- Vendors to present findings in June
- Final vendor selection targeted for July

Software Selection Process

- Initiate & Organize Project
  - Process Discovery
  - Assemble Team
  - Create Action Plan
  - Develop Timeline

- Requirements
  - Current State & Future State Descriptions
  - Develop Use Cases/Business Scenarios
  - Define & Prioritize Weighted Requirements for Functional Technical Training Quality Performance Support Maintenance

- RFP/RFI Evaluation
  - Research Vendors
  - Prepare & Issue RFP/RFI
  - Evaluate Responses & Create Shortlist

- Software Evaluation
  - Plan Demos
  - Conduct Scripted Demos or CRPs
  - Evaluate Demos/Score Vendors
  - Verify Vendor References

- Final Selection
  - Contract Negotiation
  - Due Diligence
  - Implementation
    - Strategy
    - Budget
Genetic Testing Health Plan IS Charter – RFP Scope for 2016

Comprehensive Genetic Testing Knowledge Source

Clinical Decision Support Criteria

Triple Aim Management Strategy Consultation

What inputs we need from a vendor:

- Clinical Evidence/Utility
- Specificity/Sensitivity
- Specific coding
- Estimated costs by test and lab for both single gene & panels
- Expert opinion
- Preferred Lab

- Clinical decision support tools for PA program
- Future: Clinical decision support tools for providers
- Shared Decision Making resources

- Market Intelligence
- Analytics
- New coverage policy recommendations
- Payment recommendations
- Cost recovery approaches

So that we can produce what outputs:

- Coverage Policy
- Transparent genetic testing formulary for providers and internal customers
- Accurate claim edits to enforce the formulary
- Administrative efficiency through not requiring PA for all genetic tests
- Member cost information

- Clinical criteria to support prior authorization decisions (approvals and denials)
- Language re- denial reasons
- Integrate to CarePartner (like McPartners)
- Future: Provider and member decision support tools

- New strategies to keep up with and stay ahead of the market (coverage, payment)
- Appropriate use & cost trends
- Prevent code shopping
- Optimal members experience
- Real-time pricing

---

Preliminary RFP Assessment

<table>
<thead>
<tr>
<th></th>
<th>Comprehensive Genetic Testing Knowledge Source</th>
<th>Clinical Decision Support Criteria</th>
<th>Triple Aim Management Strategy Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td>exitCore</td>
<td>![Checkmark]</td>
<td>![Checkmark]</td>
<td>![Checkmark]</td>
</tr>
</tbody>
</table>
| (since 2000; 3,000 employees) |  Prior Auth/Neatly            | Claims Studio
|                      |                               | Clinical Decision Support
|                      |                               | Case Consultation (clinical)        |
| NextDxRx             | ![Checkmark]                    | ![Checkmark]                    | ![Checkmark]                              |
| (Piloted since 2014; launch Jan 1, 2018; 50 employees) | Test & Lab Reporting
|                      | Payment Integrity
|                      | Medical Policy Support
|                      | Disease Intelligence          |

GT Steering Committee Meeting 3/21/16
Healthplan

- Coverage Policy Development & Implementation
  - One new policy
  - Two revised policies
  - New GT coding / claims committee sub-group
  - New Technology Coverage Alert (Cologuard)
- Promoting use of Laboratory Genetic Counselors
  - Contracted Clinics White Paper
- Promoting use of contracted labs
  - SBAR (in-process)
- Payment Strategy
  - New contracts with Genetic Testing laboratories targeted to achieve $1+ million in savings in 2016
- Monitoring
  - Health Informatics updating code sets used in trend analysis

Genetic Testing – Health Plan Updates

Prior Authorizations

- 59% increase in average monthly volume from July 2014 to July 2015

<table>
<thead>
<tr>
<th>Month</th>
<th>Average Monthly Prior Auth Volume (Cases)</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 2014</td>
<td>95</td>
</tr>
<tr>
<td>July 2015</td>
<td>160</td>
</tr>
</tbody>
</table>
Genetic Testing – Health Plan Updates

Prior Authorization Decisions

• 85% approved (1,646 cases)

• 15% partial/denied (300 cases)
  – Resulting in $660K estimated cost savings (2015 YTD)

HealthPlan communication

**Cologuard®**

Stool-based DNA Testing
New Technology Coverage Alert

Reasons for Alert

HealthPartners considers Cologuard® to be an experimental/investigational service.

Mayo Clinic is actively marketing Cologuard® with recent press releases.

Members are interested in Cologuard® as a non-invasive alternative to colonoscopy.

HealthPartners has received numerous appeal requests for Cologuard® denials in recent months, many of which were initiated by Exact Sciences, the test manufacturer.

Action Plan

Contracted providers will receive a reminder notice in the March 2016 edition of Fast Facts, advising them that HealthPartners considers Cologuard® to be a non-covered, experimental and investigational service.

HealthPartners Provider Relations will reach out directly to high-volume contracted providers who have recently ordered this test for their patients.
Upcoming GT Trends

- Non-Invasive Prenatal Testing (NIPT)
- Precision medicine (personalized medicine)
- Direct-to-consumer genetic testing/at-home DNA testing kits

http://nsgc.org/p/bl/et/blogaid=305

What should you do to get started?
Phase 1

- **Educate** yourself and leadership on the value of a laboratory-based genetic counselor

  Genetic testing is complex to order and interpret

  $1500 to $10,000/per test price range

  Requires documented informed consent

  Patient care dissatisfaction

Phase 2

- **Document evidence** supporting new lab genetic counselor position(s)

  - Capture patient/provider complaints stemming from genetic testing
  - Analyze annual send-out (or in house) expenses from genetic testing
  - Research benchmarks on GC review, find a subject matter expert to help (like PLUGS)
Patient-Centered Care

- System contributes to **patient care dissatisfaction**
  - High cost of care, bills surprisingly high
  - Difficulty understanding purpose and results of the test
  - Potential delays in test results (incorrect test order)
  - Patient results from reference labs (delayed) awaiting informed consent
  - No timely review or approval for genetic tests throughout the system

---

Laboratory Genetic Counselors:
A Valuable Resource for Best-Practice Care

Genetic testing is a growing trend across many healthcare specialties. It has
- At HealthPartners, health plan claim increased 50% between 2015 and 2016.
- The complexity of genetic testing and limited resources for provider education contribute to a
  30% increase revenue rate. However, 54% of academically trained physicians report feeling
  unprepared about available genetic tests and 45% feel only somewhat knowledgeable.¹

Patients can be caught in the middle if they receive genetic testing that their health plan does not cover.
- There is a wide variability of tests offered in today's marketplace. Many genetic tests are considered
  experimental/investigational and/or not medically necessary by health plans. When a laboratory bills
  the health plan, the patient may be liable for payment if there is no coverage for that test.

Laboratory Genetic Counselors help ensure that patients receive the right genetic test at the right time.
- Laboratory genetic counselors are trained to answer complex questions from care providers, review
  medical records, and assist clinicians in choosing the correct test for their patients' individualized needs. They also counsel care providers regarding when to involve a clinical genetic counselor. A clinical genetic counselor may further support the patient and care provider by facilitating an accurate interpretation of the test result and translating these results into a holistic care plan.
- At HealthPartners and Park Nicollet, laboratory-genetic counselors have determined that 14% of tests ordered between July 2015 and January 2016 were not the most appropriate test for the patient and were able to work with the care provider to discuss cancellation or modification of their order. Other institutions have reported up to 25% of orders were canceled or modified after implementation of a laboratory genetic counseling program.²

When patients receive the right test at the right time, health care facilities or health care institutions experience impressive cost-savings.
- HealthPartners and Park Nicollet lab genetic counselors have effected a total cost savings of the care group of approximately $150,000 since program implementation, with an average cost savings of $270 per test. Other institutions have reported cost-savings of up to $48,000 per month since implementing a laboratory genetic counselor program, with an average cost savings of $92 per test.³

What you can do...
- Verify that your patient’s health plan offers coverage for genetic testing services before placing orders.
- Utilize clinical genetic counselors, when available, to ensure both provider and patient are well-informed about these genetic testing options.
- Strongly consider implementing a laboratory genetic counseling program for expert assistance in making shared best-practice decisions about genetic testing for your patients.

PLUGS

Ideas. Collaboration.

Results.

Call-in toll-free number (US/Canada): 1-855-749-4750
Access code: 663 593 529

WEBEX URL:
https://focusonkidswebinars.webex.com/focusonkidswebinars/onstage/g.php?MTID=e8649e6509bd8a3c80cd13b56b18d4508

PLUGS Member of the Year 2016

Congratulations to our Laboratory Genetic Test Utilization Management Team!
Questions

• For more information contact Rick Panning @ Rick.L.Panning@HealthPartners.com