Seattle Children's®
HOSPITAL • RESEARCH • FOUNDATION

PLUGS®
Patient-centered Laboratory Utilization Guidance Services

# PLUGS®
## Patient-centered Laboratory Utilization Guidance Services

Est. 2013

# PLUGS History & Evolution

## Challenges

- ✓ High out-of-pocket cost for low-value testing, e.g., misordered genetic testing
- ✓ Labs bear the cost for the many patients who can't pay
- ✓ Issue exaggerated in pediatrics because of rare diseases

**PLUGS** evolved beyond pediatrics & genetic tests to broad laboratory stewardship advocacy

Today, we collaborate with:

- ✓ Adult and Pediatric Clinical Labs
- ✓ Lab IT and Healthcare Companies
- ✓ 3rd Party Payers including government

# PLUGS Mission & Vision

## MISSION

Improve test access, ordering, retrieval, interpretation and reimbursement.

## VISION

Be the #1 advocate for laboratory test stewardship.

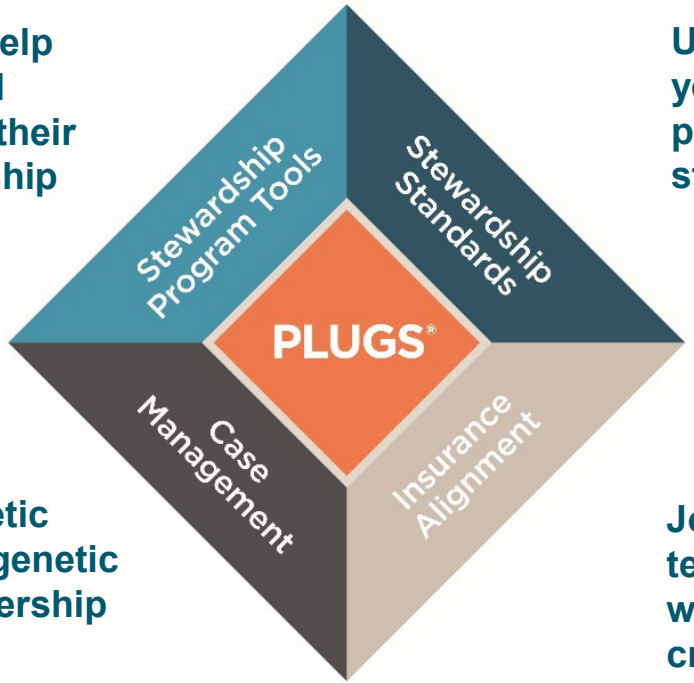
# Laboratory Stewardship

A healthcare “ethic that embodies responsible planning and management of resources”

National Research Council. Controlling Costs and Changing Patient Care?: The Role of UM. Washington, DC: The Natl Academies Press, 1989.

# PLUGS Initiatives

Tools and education to help hospital laboratories and practitioners implement their own laboratory stewardship programs.




Use the checklist to assess your laboratory stewardship program against defined stewardship standards.

Contract laboratory genetic counseling services for genetic test case review in partnership with Metis Genetics.

Join our efforts to increase testing approval for patients who meet medical necessity criteria.

# The Power of the PLUGS® Network

ACL Laboratories
Adventist Health
Aetna
Akron Children's Hospital
Arkansas Children's Hospital
Avalon Healthcare Solutions
Baptist Health
Baylor Genetics
Blue Shield of California
Boston Children's Hospital
Bronson Methodist Hospital
CentraCare Health
Children's Health
Children's Healthcare of Atlanta
Children's Hospital Colorado
Children's Hospital of Los Angeles
Children's Hospital of Philadelphia
Children's Hospital of Pittsburgh of UPMC
Children's Hospital of Wisconsin
Children's Hospitals and Clinics of Minnesota
Children's National Health System
ChristianaCare
Cincinnati Children's Hospital Medical Center
Cleveland Clinic
Concert Genetics
Cone Health
Cook Children's Medical Center
Dayton Children's Hospital
East Tennessee Children's Hospital
Fairview Health Services
Fred Hutchinson Cancer Center
Froedtert Health
Geisinger
GeneDx | Sema4
Genetic Support Foundation
Global Genes
Guardant Health
Gundersen Health System
HealthPartners (Park Nicollet / Regions and Methodist Hospitals)
Highmark, Inc.
Intermountain Healthcare
Johns Hopkins Hospital
Kaiser Foundation Health Plan of Washington
Kaiser Permanente – SCAL Region
Kaiser Permanente NW Regional Lab
LAC+USC Medical Center
Lahey Hospital and Medical Center
Le Bonheur Children's Hospital
Legacy Health
Lifespan Academic Medical Centers
Lurie Children's Hospital of Chicago
MedStar Health
Metis Genetics
MultiCare Tacoma General Hospital
Nationwide Children's Hospital
Nemours Children's Health
New York Presbyterian Hospital
Nicklaus Children's Hospital
NW Rare Disease Coalition
Ochsner Health System
Oregon Health Sciences University (OHSU)
OU Health
Parkview Health
Phoenix Children's Hospital
Project Santa Fe Foundation – Lab 2.0
Providence Health & Services
Providence Sacred Heart Medical Center
Quest Diagnostics
Rady Children's Institute for Genomic Medicine
Saint Francis Health System
Salem Health
Sanford Health
SSM Health Cardinal Glennon Children's Hospital
SSM Health St. Mary's Hospital - Madison
St. Jude Children's Research Hospital
St. Luke's
Stanford Health Care
Texas Children's Hospital
TriCore Reference Laboratories
UCLA Health
UCSF Benioff Children's Hospital Oakland
United HealthCare Services, Inc.
University of Florida Health
University of Kentucky Chandler Medical Center
University of Miami
University of Michigan Health System
University of Missouri
University of North Carolina
University of Virginia School of Medicine
UW Health University Hospital
Valley Children's Hospital
Vanderbilt University Medical Center – Vanderbilt Medical Laboratories
Versiti
Wake Forest Baptist Health
WellSpan York Hospital
Yale University – Lab Medicine

## THANK YOU TO OUR SPONSORS AND PARTNERS!

### FOUNDING PARTNER

UW Medicine
LABORATORY MEDICINE & PATHOLOGY

### GOLD

ARUP LABORATORIES
MAYO CLINIC LABORATORIES

### BRONZE

PREVENTION GENETICS part of EXACT SCIENCES
labcorp

### CORPORATE

illumina
ThermoFisher SCIENTIFIC
Clarivate™
Lucent Diagnostics A QUANTERIX BRAND

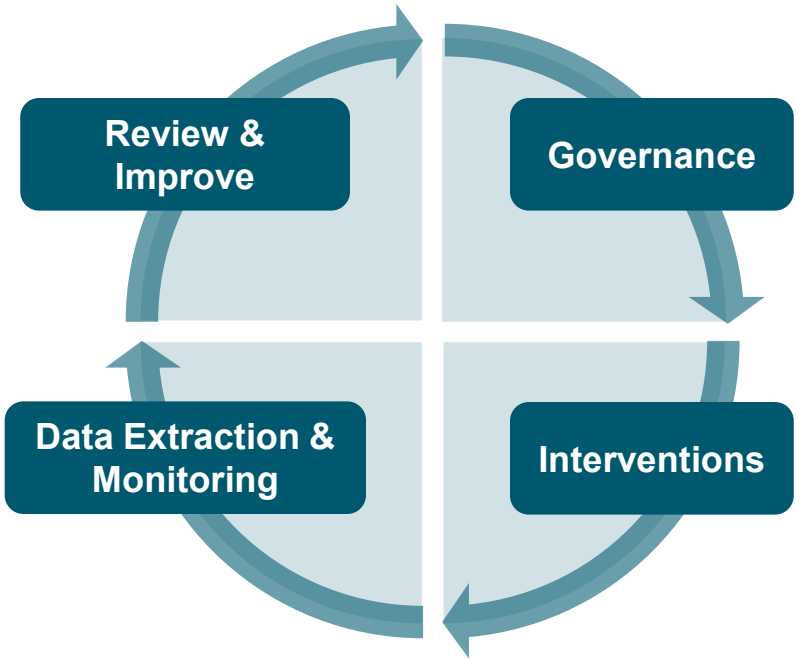
### PARTNERS

eviCore healthcare
GTA Gene Test Advisor

PLUGS® Patient-centered Laboratory Utilization Guidance Services

# Four Elements of Laboratory Stewardship Programs

**To periodically assess and improve the whole program.**




**The people who make the program happen, and the way they are organized.**

**To identify problems and assess interventions.**

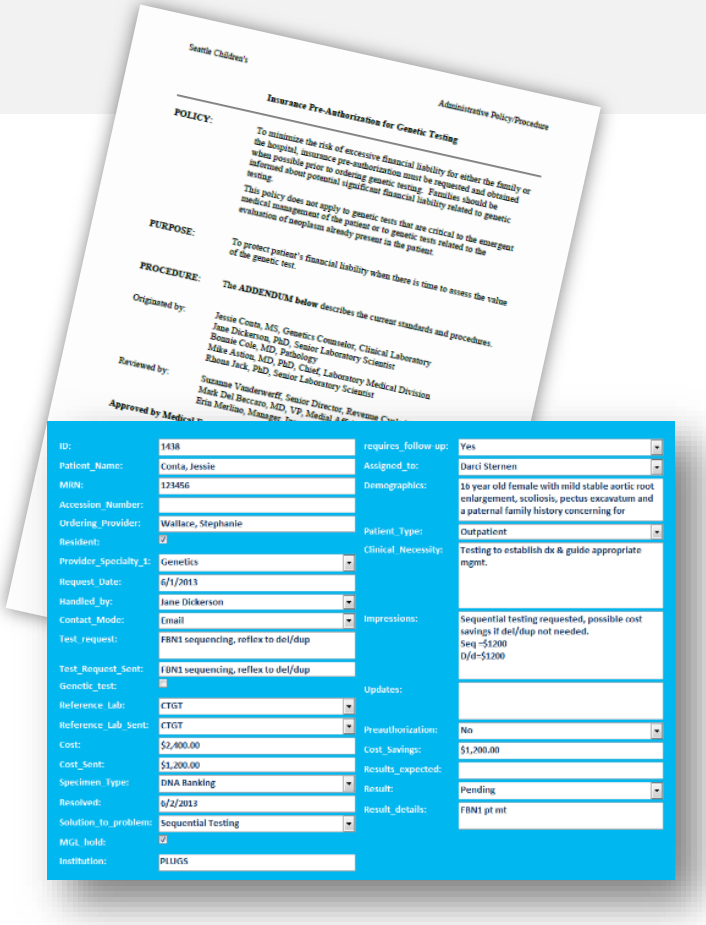
**To improve test ordering, result retrieval, accuracy of interpretation, and payment.**

Dickerson, J.A.; Fletcher, A.H.; Procop, G.W.; *et al*. Transforming laboratory utilization review into laboratory stewardship: Guidelines by the PLUGS National Committee for Laboratory Stewardship. *Journal of Applied Laboratory Medicine.* 2017; 2(2): 259-268.

PLUGS® Patient-centered Laboratory Utilization Guidance Services

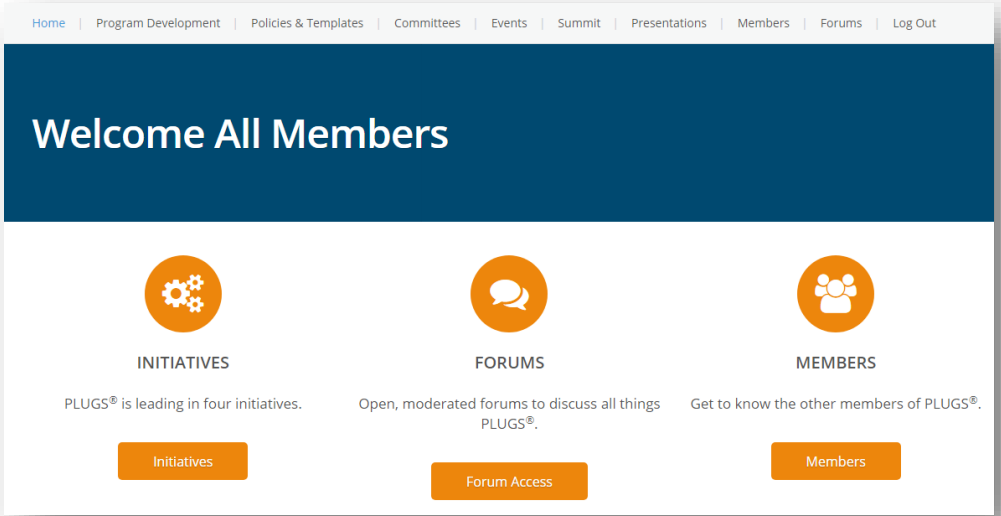
# Stewardship Program Development Tools

- ✓ Customized Strategic Assessment from the PLUGS Team
- ✓ Policies, procedures & communication templates that help providers reduce unnecessary testing & correct test orders
- ✓ Database for collecting, tracking, & analyzing cases
- ✓ Tool to assess the risk of errors in send-outs area
- ✓ Provider-satisfaction survey to solicit feedback regarding the program
- ✓ And much more…



# Be Connected

- ✓ PLUGS Committees
  - Informatics Committee
  - Insurance Alignment Committee
  - Ambassadors Committee
- ✓ Weekly Newsletter
- ✓ Quarterly Member Meetings
- ✓ Website: www.schplugs.org
- ✓ Discussion Forum
- ✓ Office Hours/Call Center



# Education

- ✓ Annual and regional conferences
- ✓ Quarterly member meetings
- ✓ Monthly webinars

PLUGS® SUMMIT

Join us for the annual PLUGS Summit, where stakeholders gather to learn practical tools for laboratory stewardship program development and insurance alignment that will apply to hospitals, health systems, reference labs, insurance payers, and patients.

The savings from eliminating unnecessary esoteric laboratory tests pays for a PLUGS membership **in about 5 days**.

**The other 360 days of savings are for your health system & your patients.**

APPENDIX 1:

# Seattle Children's Hospital Laboratory Stewardship Program

# Laboratory Test Stewardship: Four Big Problem Areas

1. Misordering tests
2. Misinterpreting test results
3. Failure to retrieve and act on test result
4. Unnecessary cost to patients and healthcare system

Source: Gandhi, TK, et al. Missed and Delayed Diagnoses in the Ambulatory Setting… Ann Int Med. 2006;145(7).

# Laboratory Test Stewardship

Refers to a healthcare “ethic that embodies responsible planning and management of resources”

$$\text{Value} = \frac{\text{Quality}}{\text{Cost}}$$

Source: National Research Council. *Controlling Costs and Changing Patient Care?:* The Role of UM. Washington, DC: The Natl Academies Press, 1989.

# Lab Stewardship Interventions

**Table 1. Stewardship intervention examples by strength.**

| Gentle | Medium | Strong |
|---|---|---|
| Posting guidelines on the requisition | Utilization report cards | Utilization report cards with peer or leadership review |
| Computerized reminders regarding utilization guidelines | Changes to manual requisitions | Privileging specific tests to specialty providers |
| Educational lectures | Hiding tests in CPOE systems | Laboratory formulary including send-out formulary |
| Consensus reference laboratory preselection for specialized testing | Periodically reviewing and updating physician preferences | Requirement for high-level approval or consultation |
| Providing relative cost information in CPOE | | Rules requirement<br>CPOE: Hard stops |

**Gentle Guidance** → → → **Strong Guidance**

Dickerson, J.A.; Fletcher, A.H.; Procop, G.W.; *et al*. Transforming laboratory utilization review into laboratory stewardship: Guidelines by the PLUGS National Committee for Laboratory Stewardship. *Journal of Applied Laboratory Medicine*. 2017; 2(2): 259-268.

# Case

**Patient** — 12 y/o inpatient with hypoglycemia secondary to hyperinsulinism and associated seizures evaluated by Endocrinology

**Testing** — Genetic testing recommended to work up possible genetic etiology vs. insulinoma

**Order** — Requested concurrent analysis of 8 genes including “GLUT-1”

**Review** — Error caught on review by lab test stewardship genetic counselor

**GLUT-1**
*(glucose transporter type-1)*
***SLC2A1* gene**
**De Vivo disease**

**Order Modified** →

**GLUD-1**
*(glutamate dehydrogenase-1)*
***GLUD1* gene**
**Hyperinsulinemic hypoglycemia**

# Interventions at SCH

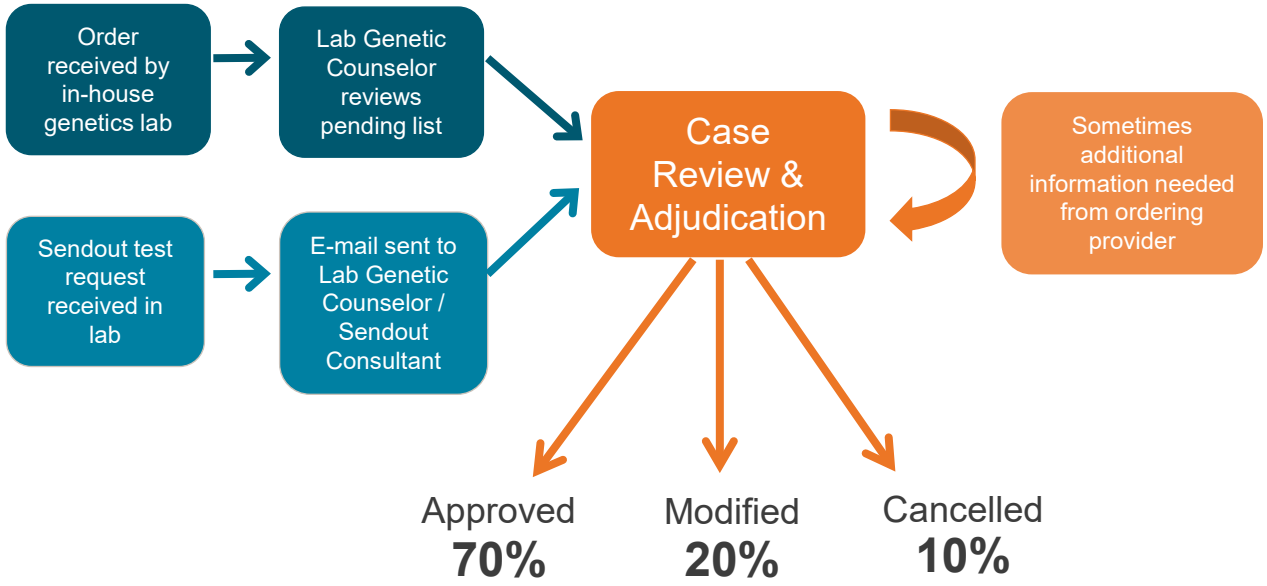
## HYPOTHESIS

By implementing a review process for expensive genetic sendout tests, we will save $ and improve value for patients.

### Sample Test Review Criteria

- ✓ All Miscellaneous requests
  - ✓ Requests to send to non-preferred laboratory
  - ✓ Requests to send to international laboratories
  - ✓ Requests to send tests performed in-house
- ✓ All genetic send out tests
- ✓ Tests defined as under management

# Case Review Process at Seattle Children's…




*Based on Seattle Children's Hospital data

# Lab Genetic Counselors Review Genetic Test Orders

## ~30% order modification/cancellation rate

- Cancellations include duplicate testing and tests that are not medically necessary.
- Modifications include correcting erroneous test orders and improving an order.
- >$3 million in cost avoidance since 2011, with 50% accruing to patients and 50% to organization.

# Case Review ROI

## Cost-Avoidance Model for Genetic Test Review:*

- 10 requests/week ($1330 average charge per test)
- 30 minutes/request
- 30% modification rate
- $100 saved/request
- **ROI:** $1000 saved/week with 5 hr consultant time/week=
  - $52,000 saved/yr - ~$11,250 consultant salary/yr**)=
  - **$40,750 annual cost avoidance**

* Data from Seattle Children's Hospital 2022-2023 genetic test sendout case review, N= 5808.

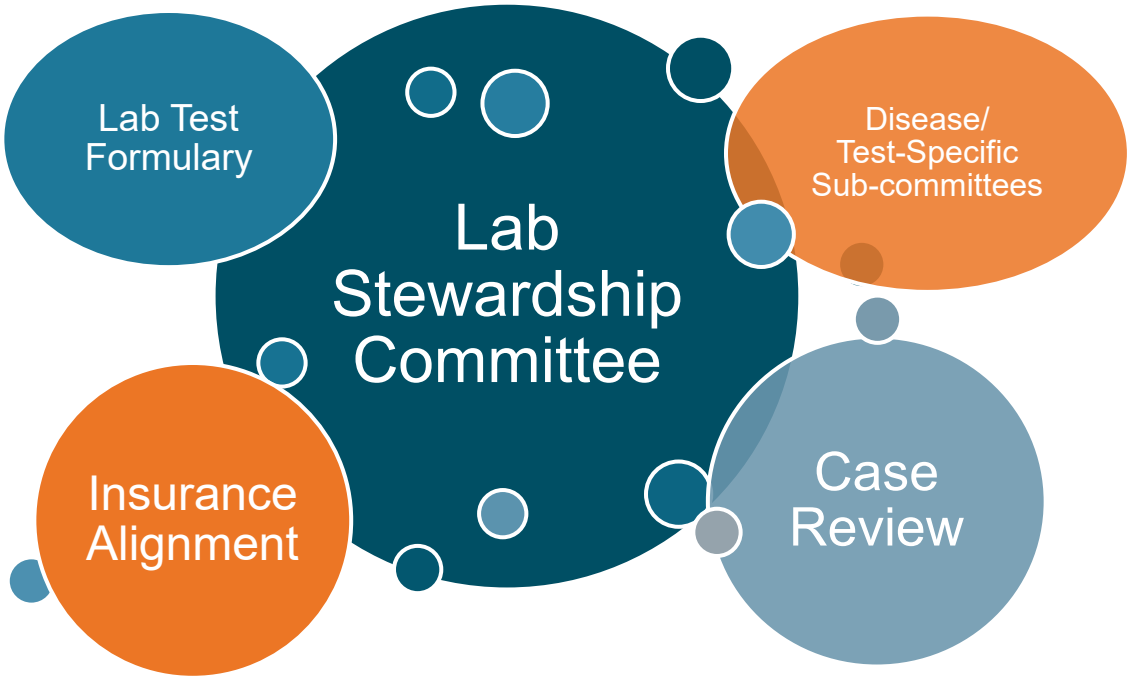
** Estimates to illustrate example using annual GC salary of $90K. Specific costs per test, salary details, and cost-avoidance will vary and are unique to each institution.

# Surveys Reveal Positive Provider Response

I really appreciate the efforts of the UM team. **Given the state of our health care 'system'** we definitely need a **team of experts** to navigate these challenging waters!

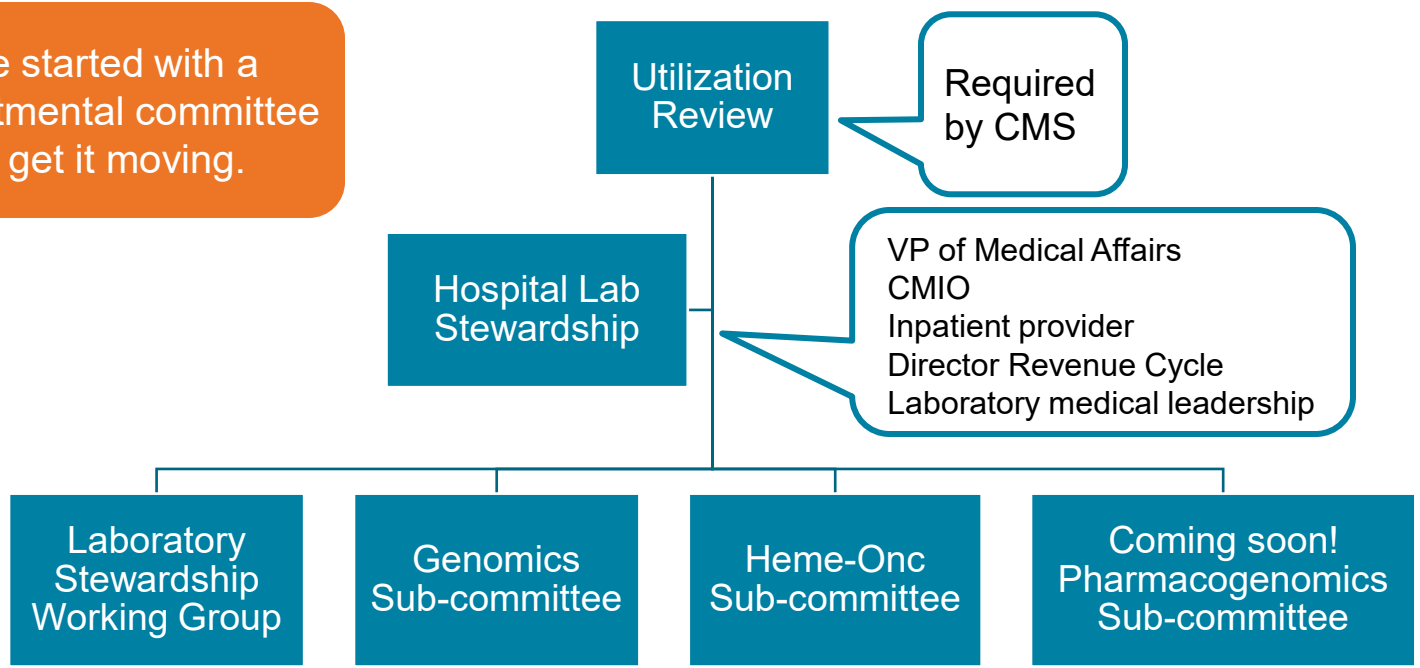
I think the lab UM team overall is doing a phenomenal job. Their **services are definitely helpful**, if not necessary, for genetics and non-genetic providers alike **to appropriately plan and carefully select laboratory tests**.

# SCH Lab Stewardship Program



# Lab Stewardship Committee Hierarchy

We started with a departmental committee to get it moving.



# Laboratory Stewardship Committee

- **Meets Bi-Weekly**
- **Committee includes:**
  - Pathologists, clinical chemists, laboratory genetic counselors, specialty labs manager, lab business operations manager, medical geneticists, clinical genetic counselors
- **Weekly working meeting includes:**
  - Case review
  - Test build & reference lab discussions (e.g. lab formulary)
  - Focused intervention project development/management

"No, it's too late for the oversight committee, send it to the hindsight committee."

# Hospital Laboratory Stewardship Committee

- **Meets Quarterly (or as needed)**
- **Established Jan 2017**
  - High-level decision making:
  - Clinician Test Requests (Pleximmune)
  - Peri-mortem genetic testing policy
  - “Free” testing policy
  - Policies/coverage for rapid exomes/genomes and tumor testing

**WHO:**

VP of Medical Affairs
CMIO
Inpatient provider
Director Revenue Cycle
Laboratory medical leadership

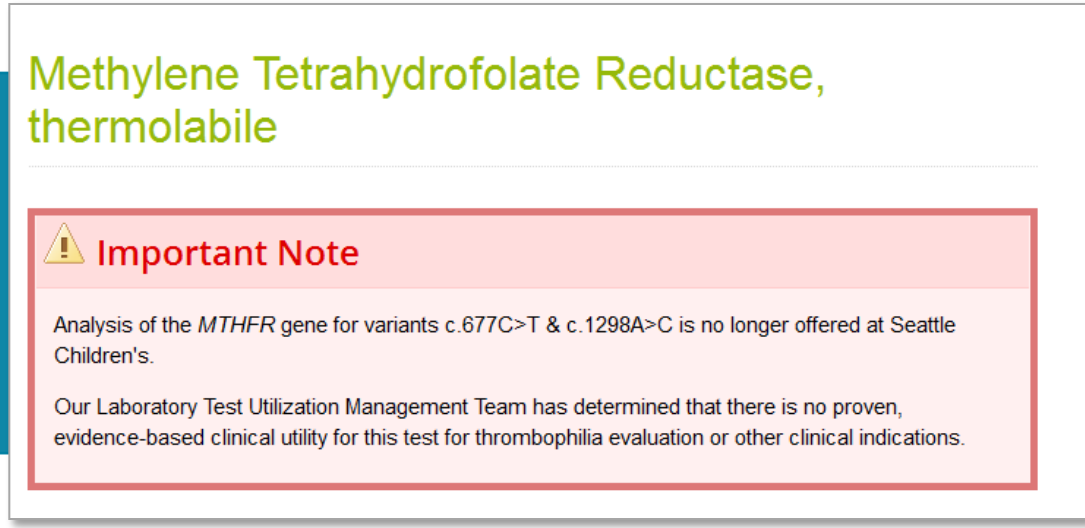
# Initiatives

## Improve lab test formulary:

- ✓ Monitor Miscellaneous tests & determine when to build
- ✓ Guide systematic process for removing tests from the menu

**Example: MTHFR**

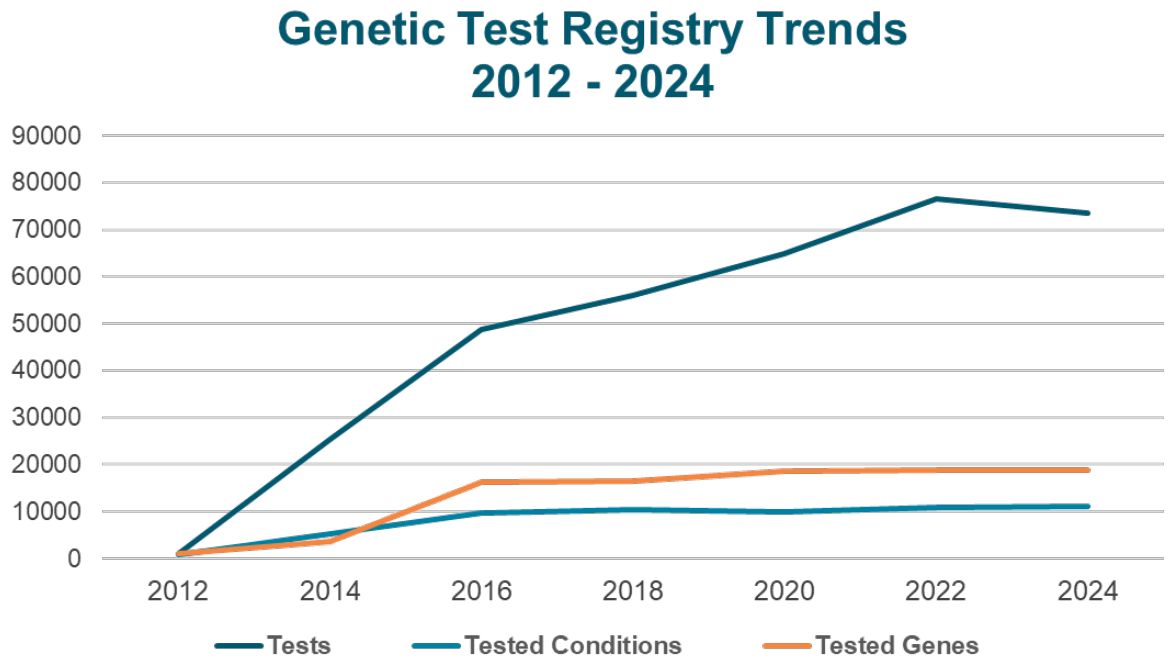
- Notification process for providers, families & lab staff
- Improved patient care, reduced provider frustration, & reduced cost



APPENDIX 2:

# Case Management

# Making the Case for Case Management




GTR: Genetic Test Registry https://www.ncbi.nlm.nih.gov/gtr

# Case Management from Reference Labs

RESEARCH ARTICLE

AMERICAN JOURNAL OF medical genetics PART A

Genetic Counselor Review of Genetic Test Orders in a Reference Laboratory Reduces Unnecessary Testing

Christine E. Miller,* Patti Krautscheid, Erin E. Baldwin, Tatiana Tvrdik, Amanda S. Openshaw, Kim Hart and Danielle LaGrave

Genetics Division, ARUP Laboratories, Salt Lake City, Utah

Manuscript Received: 1 May 2013; Manuscript Accepted: 3 January 2014

COMMUNIQUÉ

Test Utilization and Appropriate Test Orders:

The Role of the Genetic Counselor

AJMG AMERICAN JOURNAL OF medical genetics PART A

Explore this journal >

RESEARCH LETTER

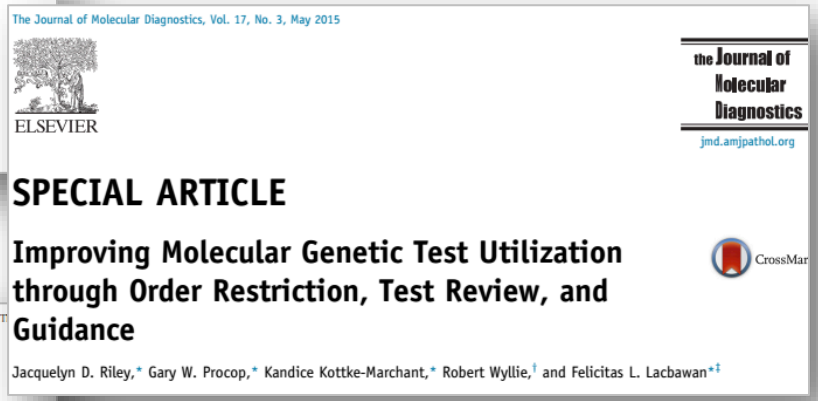
Adding value to genetic testing through utilization management: Commercial laboratory's experience

Gina K. Londre MS, Christina A. Zaleski MS, Jessie H. Conta MS

# Case Management in the Hospital Setting

Improving the Value of Costly Genetic Reference Laboratory Testing With Active Utilization Management

Jane A. Dickerson, PhD; Bonnie Cole, MD; Jessie H. Conta, MS; Monica Wellner, BS; Stephanie E. Wallace, MD; Rhona M. Jack, PhD; Joe Rutledge, MD; Michael L. Astion, MD, PhD



The Journal of Molecular Diagnostics, Vol. 17, No. 3, May 2015

ELSEVIER

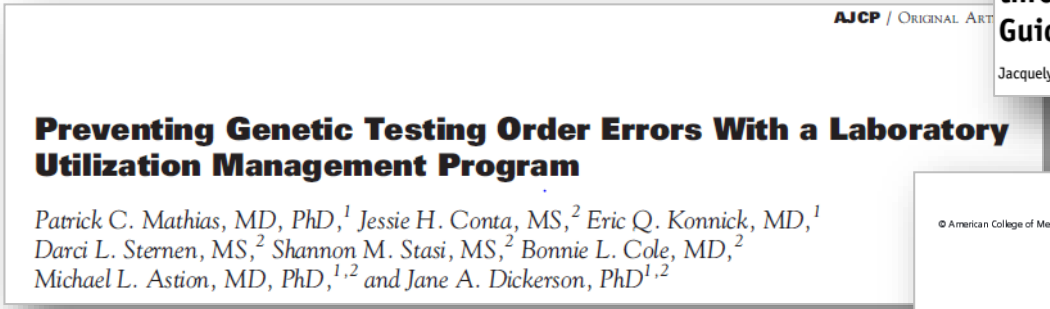
the Journal of Molecular Diagnostics

jmd.amjpathol.org

SPECIAL ARTICLE

Improving Molecular Genetic Test Utilization through Order Restriction, Test Review, and Guidance

Jacquelyn D. Riley,* Gary W. Procop,* Kandice Kottke-Marchant,* Robert Wyllie,† and Felicitas L. Lacbawan*‡



AJCP / Original Art

Preventing Genetic Testing Order Errors With a Laboratory Utilization Management Program

Patrick C. Mathias, MD, PhD,[1] Jessie H. Conta, MS,[2] Eric Q. Konnick, MD,[1] Darci L. Sternen, MS,[2] Shannon M. Stasi, MS,[2] Bonnie L. Cole, MD,[2] Michael L. Astion, MD, PhD,[1,2] and Jane A. Dickerson, PhD[1,2]

© American College of Medical Genetics and Genomics

ORIGINAL RESEARCH ARTICLE | Genetics inMedicine

Promoting appropriate genetic testing: the impact of a combined test review and consultative service

Carlos J. Suarez, MD[1], Linbo Yu, MS[2], Natalie Downs, MS[2], Helio A. Costa, PhD[3] and David A. Stevenson, MD[4]

METIS GENETICS

GENETIC COUNSELING MADE SIMPLE

PLUGS

Laboratory Utilization Guidance Services

# Optimize Your Lab Test Stewardship Program

**Do you want to perform genetic test stewardship but lack the Genetic Counselor resources ?**

# GeneTestAdvisor can help

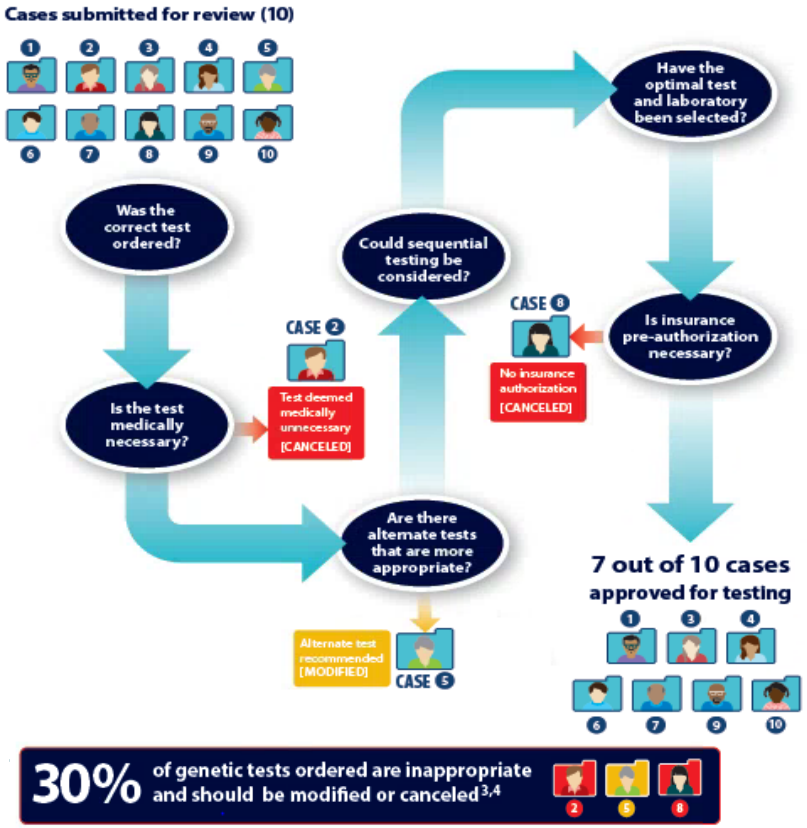

## GeneTestAdvisor (GTA)

**Genetic counselors helping optimize genetic test selection**

Created in collaboration between Metis Genetics® and PLUGS®,
**GTA is a genetic test stewardship service providing:**

- **Medical necessity**
- **Optimal test selection**
- **Cost efficiency**

# GeneTestAdvisor: Our Process

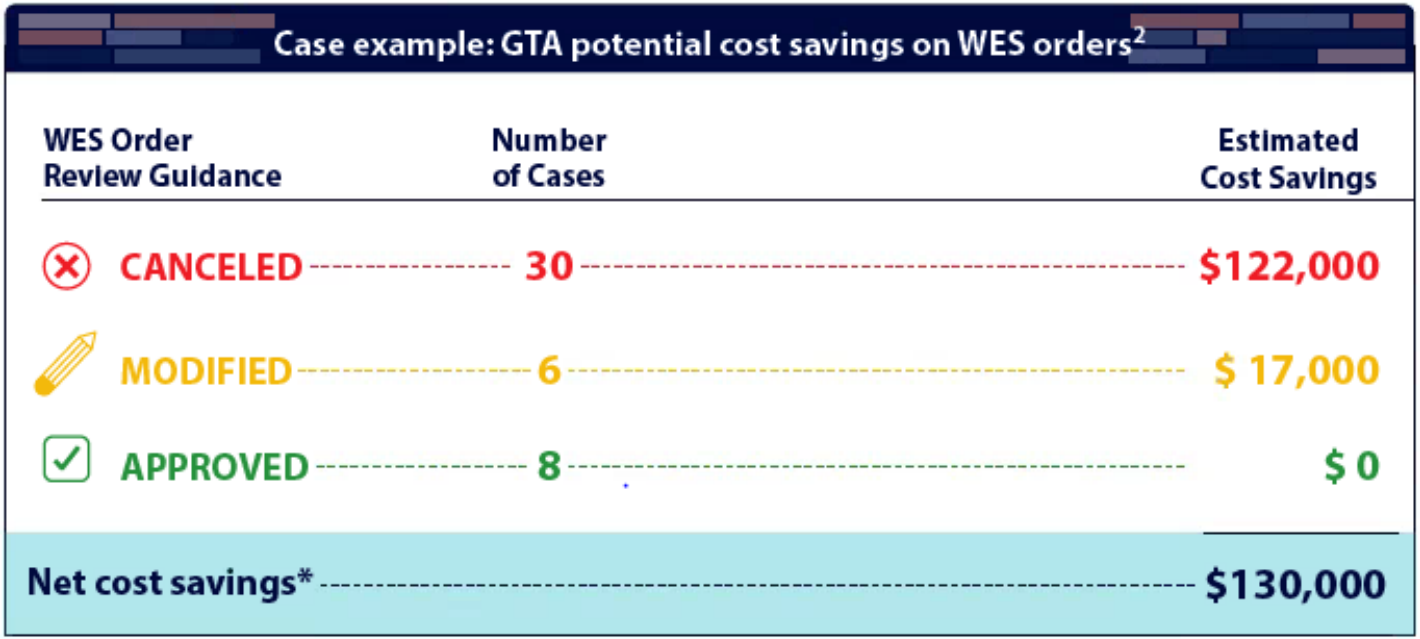



- Customizable yet systematic approach
- Follow existing processes
- Interaction with ordering provider to define optimal test selection
- Prioritize medical necessity and professional guidelines
- Request appropriate clinical documentation

METIS GENETICS

PLUGS® Patient-centered Laboratory Utilization Guidance Services

# Case Study: Texas Children's Hospital




The above example is based on simulated prospective case review of Whole Exome Sequencing (WES) orders. Estimated test charges were $3000–$4500 for WES, based on the average charge at three major reference laboratories; and $890–$2500 for panel tests.

*Net cost savings was calculated after case review fee applied.


Conway ME, Kalejta CD, Sternen DL, Singh IR. The Importance of Genetics Experts in Optimizing Genetic Test Orders Through Prospective and Retrospective Reviews. *Am J Clin Pathol*. 2020;153(4):537-547. doi:10.1093/ajcp/aqz188

# Return on Investment

## GeneTestAdvisor pays for itself.

**30%**

**Average modification rate**

Includes:

- Recommendation of different test or less expensive test
- Cancelling order

**$ Review**

**Cost savings per review**

Dependent upon:

- Average test cost
- Ordering department
- Insurance contracts

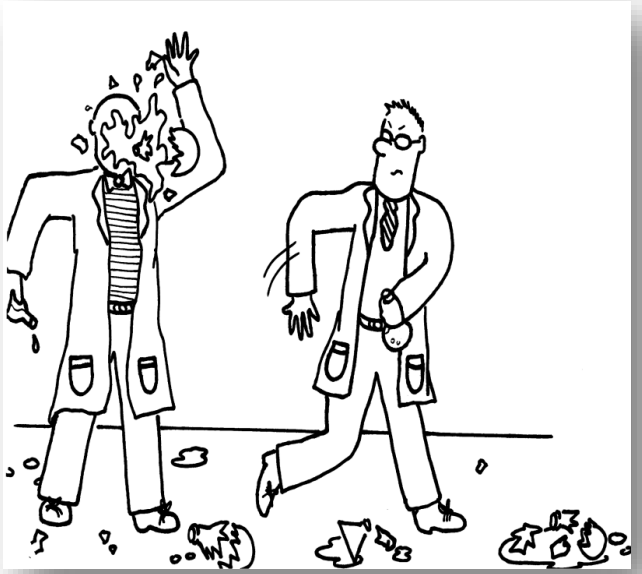
APPENDIX 3:

# Insurance Alignment

# PLUGS Beliefs

- Understanding the insurance industry enables collaboration for fair payment for patients, labs, and insurers.

- The average lab or hospital executive is not more (or less) intelligent or ethical than the average insurance executive.



Lab and insurance executives in friendly debate over medical necessity

# Patient Financial Bill of Rights

- … an itemized bill
- … protection from surprise out-of-network bills
- … understand the provider network in the health plan
- … a stable network
- … know conflicts of interest
- … know facility fees
- … see the price list!
- … be offered cheaper options
- … avoid a collection agency

Rosenthal E. Nine Rights Every Patient Should Demand: We need a Financial Bill of Rights to protect consumers of health care from unfair charges. *New York Times* April 27, 2018.
www.nytimes.com/2018/04/27/opinion/sunday/patients-rights-hospitals-health-care.html

# Challenges Faced by Insurers

- Coding: don't know what they are buying
- High cost/unit for genetic tests, PLAs
- Should they pay for DTC testing?
- Test ordering errors
- Lack lab experts to write policies

- Tests without proven clinical utility
- Billing abuses by labs
  - "free" testing
  - tendency to bill largest panel (respiratory, GI, tox)
  - billing below costs…
- Need for innovative partnerships regarding evidence accumulation

Source: Interviews by Dr. Dan Anderson and Mike Astion
More than a CPT Code: An interview with Matthew Fickie. *Clinical Laboratory News*, April 2019.
www.aacc.org/publications/cln/articles/2019/april/more-than-a-cpt-code-a-view-on-genetic-testing-from-inside-a-health-plan

# Three Strategies to Improve Insurance Coverage

1. Collaborate with insurers to…
   - ↓ ↓ fraud, waste, and abuse
   - update medical policies
2. Share best practices to reduce administrative burden and align insurance work with stewardship practices
3. Help patients win ethical insurance grievances

# PLUGS Medical Policy Work: Philosophy

- ✓ Don't be afraid to **land a narrow policy where no policy exists**
- ✓ **Partner with everybody**: IVD (e.g., Illumina), labs, insurers
- ✓ Make as many **policies freely available** as possible
- ✓ **Praise insurers** who keep up to date with evidence


http://6sme.com/blog/2017/08/01/the-secrets-to-success/

# PLUGS Medical Policy Work

These PLUGS® policies were developed by experts within the PLUGS network and are intended for use by insurance payers, laboratories, providers, families, and consumer groups to guide coverage and reimbursement for medically appropriate genetic tests.

- ✓ Genomic Sequencing in Rare Disease Policy
- ✓ Rapid Genome Sequencing Policy
- ✓ Epilepsy Genetic Testing Policy
- ✓ Inherited Bone Marrow Failure Syndromes Policy
- ✓ MELAS Genetic Testing Policy
- ✓ MERFF Genetic Testing Policy
- ✓ Mitochondrial Genetic Testing Policy
- ✓ Mitochondrial DNA Deletion Syndromes Genetic Testing Policy
- ✓ LHON Genetic Testing Policy
- ✓ MNGIE Genetic Testing Policy
- ✓ NARP Genetic Testing Policy

https://www.schplugs.org/insurance-alignment/

PLUGS® Patient-centered Laboratory Utilization Guidance Services

# Coding Conundrums

- Lack of specificity of codes in many domains of lab testing
- # of panel **codes** (~40 GSP codes) ≠ # of panel **tests** (WAY more)
- Evolving complexities, including Proprietary Laboratory Analyses (PLA) Codes


**Annual increase in PLA codes**

# Code Submission for Epilepsy Gene Panel

- Working group from PLUGS Insurance Alignment Committee
- Experts represented a variety of perspectives
- Application for GSP (genomic sequencing procedure) code submitted with support from the American Academy of Neurology
- Code approved! Included in the 2021 CPT code set


**GSP-Epilepsy 81419**

**CPT® Smart App**

Submit an online application with the CPT® Smart App.

Start Your Application

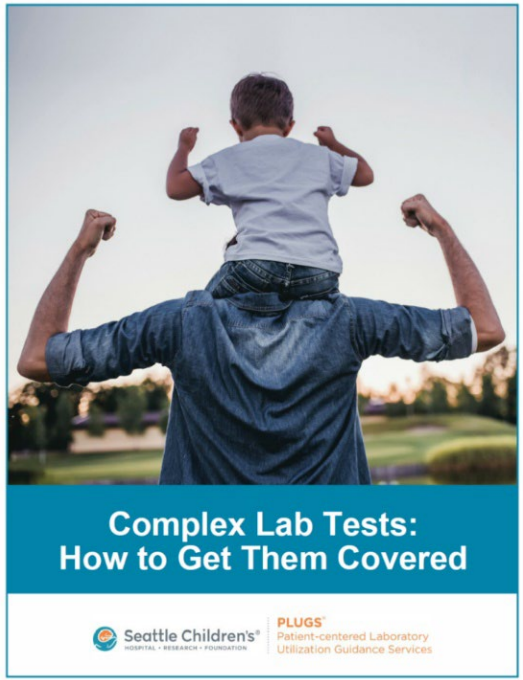
https://www.ama-assn.org/practice-management/cpt/cpt-code-change-applications

# PLUGS Preauthorization Toolkit

- Working group from PLUGS Insurance Alignment Committee
- Experts represented a variety of perspectives
- Tool includes practical guidance for insurance preauthorization coordination & workflows

## TABLE OF CONTENTS

# Support for a Successful Grievance




**Patient & family tool that provides information about payment systems for complex lab tests & guidance/checklists on navigating an appeal.**

Feedback from patients & families:

*"I wish I would have had access to this guide during my years of struggle to get a diagnosis, it would have made my life a lot easier."*

*"The checklists are extremely helpful and synthesize large amounts of complex information."*

schplugs.org/plugs-patient-toolkit/

PLUGS® Patient-centered Laboratory Utilization Guidance Services

# Insurance Alignment Committee

## Systematic Solutions
to improve preauthorization processes/workflow

- ✓ Standardize workflow within institution
- ✓ Right person doing right work
- ✓ Align approach with payer systems
- ✓ Focus on stewardship at all steps

## Coding Transparency

- ✓ Obtain new CPT codes to improve coding transparency
- ✓ Provide evidence reviews for PLA codes

## Policy Creation & Improvement

- ✓ Develop rational policies using experts
- ✓ Distribute policies
- ✓ Create infrastructure to ensure policies are kept up-to-date

# Insurance Alignment: Systematic Solutions

Le Bonheur Children's Hospital

Standard SOP for genetic testing preauthorization

Seattle Children's® HOSPITAL • RESEARCH • FOUNDATION

Robust case review process during preauthorization and order triage.

Children's Hospital of Pittsburgh of UPMC

Strong partnership with local payer resulted in significant improvement in authorization & reimbursement for exome sequencing

Children's Hospital LOS ANGELES℠

Streamlined process that is integrated in Cerner and improves insurance reimbursement rates, reduces time required to obtain authorization and significantly improves efficiency