

# **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 laboratory test access, ordering, retrieval, interpretation and reimbursement

### **VISION**

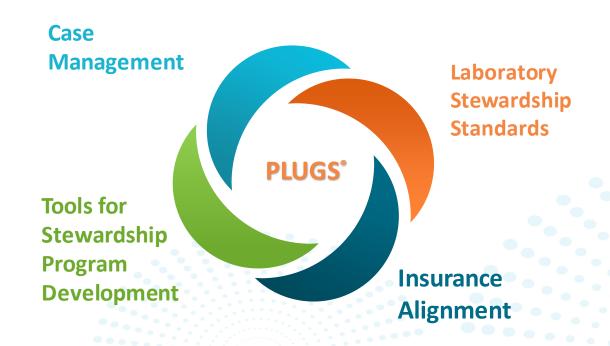
Be the #1 advocate for laboratory test stewardship.

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





### **PLUGS Initiatives**







### **PLUGS Initiatives**

- ✓ **Laboratory Stewardship Program Guidance, Tools & Education** to help hospital laboratories and practitioners implement their own laboratory stewardship programs. These programs improve patient safety by reducing errors, and significantly reduce laboratory testing expenses.
- ✓ **Insurance Alignment** to guide national consensus policies related to laboratory tests and framework and guidance to build partnerships with local payers to improve efficiencies around test review and improve reimbursement outcomes. This will ultimately increase testing approval for patients who meet medical necessity criteria.
- ✓ Case Management service for genetic tests is provided in partnership with Metis Genetics to clients who are interested in contracting additional laboratory genetic counseling services for case review.
- ✓ Laboratory Stewardship Standards created by the National Committee for Laboratory Stewardship (NCLS) will include checklists for promoting and formalizing laboratory stewardship programs. The core elements will also be helpful for independent commercial clinical laboratories.



### The Power of the PLUGS Network

ACL Laboratories

Aetna

AiLife Diagnostics, Inc. Akron Children's Hospital

Arkansas Children's Hospital

**Baylor Genetics** 

Blue Shield of California

Boston Children's

Bronson Methodist Hospital

Centra Care 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

Cook Children's Medical Center

Concert Genetics

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)

Intermountain Healthcare

Johns Hopkins Hospital

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 Mercyhealth

Metis Genetics

Mountain States Regional Genetics Network

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)

**Pathnostics** 

Penn Medicine

Phoenix Children's Hospital Providence Health & Services

Providence Sacred Heart Medical Center

Quest Diagnostics

Rady Children's Institute for Genomic Medicine

Saint Francis Health System

Sanford Health

Southern Illinois Healthcare

SSM Health Cardinal Glennon Children's Hospital SSM Health St. Mary's Hospital - Madison

St. Jude Children's Research Hospital

St. Louis Children's Hospital

St. Luke's

Stanford Healthcare

Stormont Vail Health Laboratory

Sutter Health

Texas Children's Hospital

TriCore Reference Laboratories

TriHealth

UC Davis Health

**UCLA** Health

UCSF Benioff Children's Hospital Oakland

University of Florida Health

University Of Kentucky Chandler Medical Center

University of Michigan Health System

University of Missouri

University of North Carolina

University of Virginia School of Medicine

University of Washington

UW Health University Hospital Valley Children's Hospital

Versiti

Wake Forest Baptist Health

Wellspan

#### THANK YOU TO OUR SPONSORS AND PARTNERS: **GOLD BRONZE**

























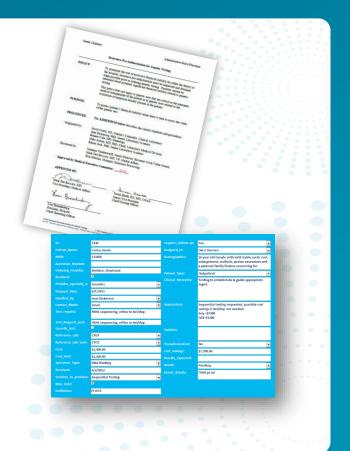






# Stewardship Program Development Tools

- ✓ 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...

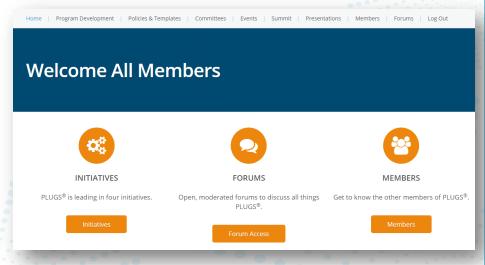






### Be Connected

- ✓ PLUGS Committees
  - National Committee for Laboratory Stewardship (NCLS)
  - Informatics
  - Insurance Alignment
- ✓ Weekly Newsletter
- ✓ Monthly Member Meetings
- ✓ Website: www.schplugs.org
- ✓ Discussion Forum
- ✓ Office Hours/Call Center







### Education

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





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 will pay 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 Lab Stewardship Program





# Test Utilization: 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





# Laboratory Test Stewardship

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

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







# Lab Stewardship Interventions

#### LEVELS OF GUIDANCE

#### Gentle

- Posting of guidelines on the requisition
- Computerized reminders regarding utilization guidelines
- ✓ Educational lectures
- Consensus reference laboratory pre-selection for specialized testing
- Providing relative cost information in CPOE

#### Medium

- ✓ Utilization report cards
- Changes to manual requisition
- ✓ Hiding tests in computerized provider order entry systems
- Periodically reviewing and updating physician preferences

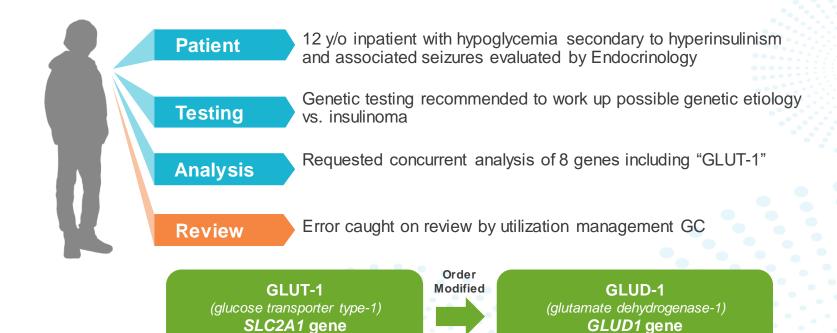
#### Strong

- Privileging specific tests to specialty providers
- ✓ Lab test formulary
- Utilization report card with peer or leadership review
- ✓ Requirement for highlevel approval (e.g. Pathologist) or consultation (e.g. genetic counselor)
- ✓ CPOE: Hard stops





### Case



Hyperinsulinemic hypoglycemia





De Vivo disease

# Interventions at SCH

#### HYPOTHESIS

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

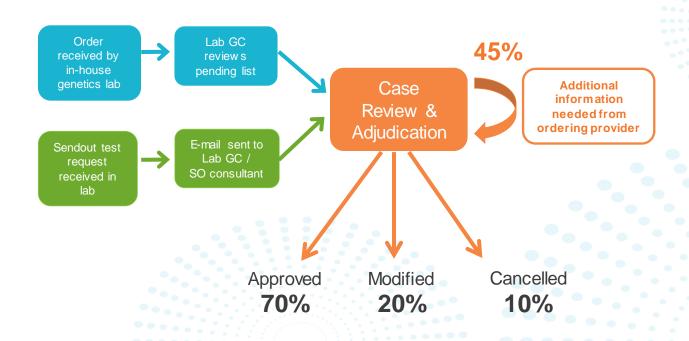
# Sample Test Review Criteria

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



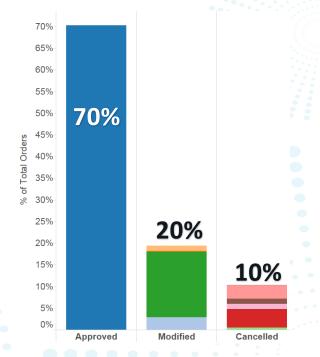


### Case Review Process at Seattle Children's...



# Seattle Children's: Lab genetic counselor review of genetic testing produces steady 30% order modification/cancellation rate

- Reasons for cancellation include duplicate testing and "not medically necessary"
- Modifications include <u>correcting erroneous</u> test orders and improving an order.
- >\$2 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 (\$1560 average charge per test)
- 30 minutes/request
- 25% modification rate
- \$180 saved/request
- **ROI:** \$1800 saved/week with 5 hr consultant time/week=
  - \$93,600 saved/yr ~\$11,180 consultant salary/yr\*\*)=
  - \$82,220 annual cost avoidance

<sup>\*\*</sup> 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.





<sup>\*</sup> Data for FY19 genetic test case review at Seattle Children's Hospital, N=1548.

# 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.





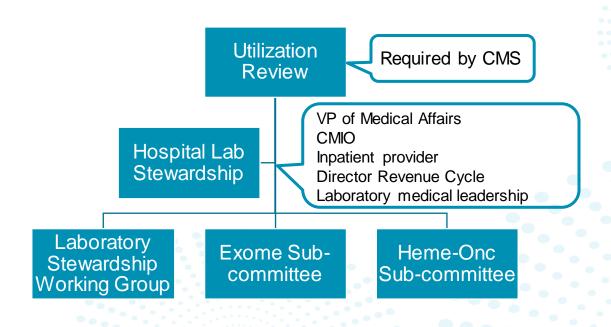




# SCH Lab Stewardship Program



# Committee Hierarchy







# Hospital Laboratory Stewardship at SCH

- Established Jan 2017
- Meets quarterly
- High-level decision making:
  - ✓ Clinician Test Requests (Pleximmune)
  - ✓ Peri-mortem genetic testing policy
  - ✓ "Free" testing policy
  - Policies/coverage for rapid exomes and tumor testing
  - Best-practice guideline for autoimmune encephalopathy

#### WHO:

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





# Laboratory Stewardship Working Group

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





### **Initiatives**

### Improve lab test formulary:

- ✓ Monitor MISC 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

### Methylene Tetrahydrofolate Reductase, thermolabile

#### Important Note

Analysis of the MTHFR gene for variants c.677C>T & c.1298A>C is no longer offered at Seattle Children's.

Our Laboratory Test Utilization Management Team has determined that there is no proven, evidence-based clinical utility for this test for thrombophilia evaluation or other clinical indications





#### **APPENDIX 2:**

# **Case Management**

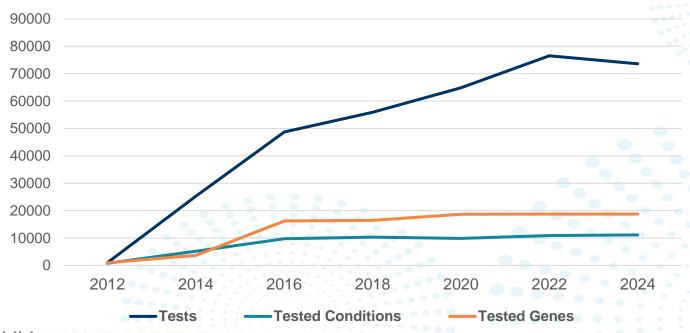




Laboratory Utilization Guidance Services

# Making the Case for Case Management









# Case Management from Reference Labs

#### RESEARCH ARTICLE



#### 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



Test Utilization and Appropriate Test Orders:

The Role of the Genetic Counselor



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

the Journal of Molecular Diagnostics

jmd.amjpathol.org

#### SPECIAL ARTICLE

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



Preventing Genetic Testing Order Errors With a La Utilization Management Program

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

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

**ORIGINAL RESEARCH ARTICLE** 

Genetics in Medicine

American College of Medical Genetics and Genomics

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

Carlos J. Suarez, MD¹, Linbo Yu, MS², Natalie Downs, MS², Helio A. Costa, PhD³ and David A. Stevenson, MD⁴





# 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:





**Optimal test selection** 



**Cost efficiency** 







# GeneTestAdvisor can help



**Healthcare Systems** 



**Patients** 



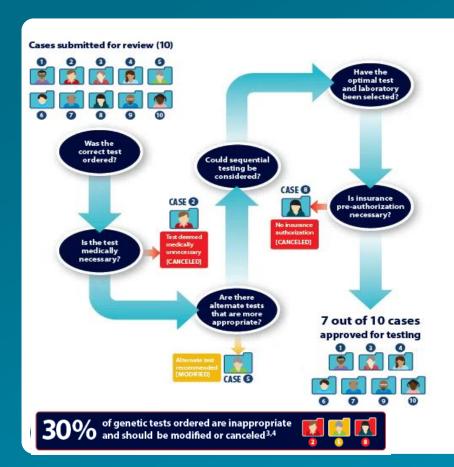
**Payers** 







### 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



# Case Study: Texas Children's Hospital

WES Order Review Guidance	Number of Cases	Estimated Cost Savings
× CANCELED	30	\$122,000
MODIFIED	6	\$ 17,000
APPROVED	8	\$ o

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.

<sup>\*</sup>Net cost savings was calculated after case review fee applied. See reference 2.







### Return on Investment

### GeneTestAdvisor pays for itself.



**Average modification rate** 

#### Includes:

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



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
- 2. ... protection from surprise out-ofnetwork bills
- ... understand the provider network in the health plan
- 4. ... a stable network

- 5. ... know conflicts of interest
- 6. ... know facility fees
- 7. ... see the price list!
- 8. ... be offered cheaper options
- 9. ... to avoid a collection agency





### 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





# 3 strategies to improve insurance coverage

- 1. Collaborate with insurers to...
  - ↓ ↓ fraud, waste, and abuse
  - update medical policies
- 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





### 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



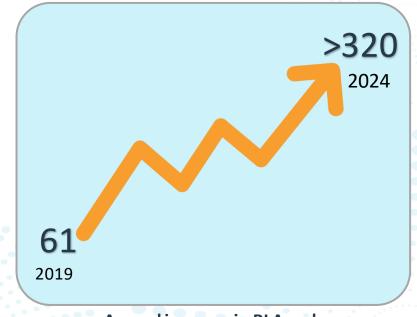


### Coding Conundrums

 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 81XX6**

Add genomic sequencing procedure code 81XX6 for reporting epilepsy gene panel

#### **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**

#### I. Laboratory Stewardship

Laboratory Stewardship for Genetic Tests
Current Procedural Terminology (CPT) Codes
Coding Genetic Tests: Multi-Gene Panels, Exome Sequencing, & PLA
Codes

#### II. Preauthorization

The Basics
The Appeals Process
External Review

#### III. Implementing a Preauthorization Process

Introductory Assessment Questionnaire Workflow Considerations External Resources for Preauthorizations

#### IV. Payer Policies, Medical Necessity, & Documentation

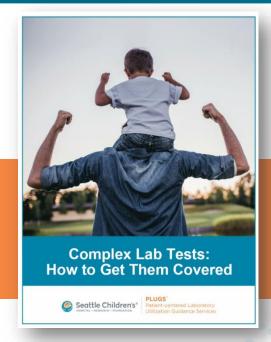
Navigating Payer-Specific Policies Medical Necessity Documentation and Required Test Rationale

V. Partnering with Payers to Reduce Administrative Burdens





### Support for a successful grievance



We developed a tool for patients & families 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/







# Insurance Alignment Committee



Systematic Solutions to improve preauth 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 upto-date





# Insurance Alignment: Systematic Solutions



Standard SOP for genetic testing preauthorization



Robust case review process supports efforts to obtain exemption from payer preauthorization process



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



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





# National Committee for Laboratory Stewardship (NCLS)





### National Committee for Laboratory Stewardship

### **MISSION**

Improve the quality and value of clinical care through establishing national standards for laboratory test utilization

### **VISION**

To promote and enable the highest standards of effective test utilization in every clinical setting

Committee members:

Mike Astion Rob Carpenter Jane Dickerson Andrew Fletcher Paula Santrach Brian Jackson Gary Procop Lee Schroeder Ila Singh





#### Guidelines Published in J. of Applied Laboratory Medicine



Transforming laboratory utilization review into laboratory stewardship: Guidelines by the PLUGS National Committee for Laboratory Stewardship

#### Four basic elements of lab stewardship programs:

- 1 Governance
- 2 Interventions
- 3 Data extraction and monitoring
- 4 Review and improve

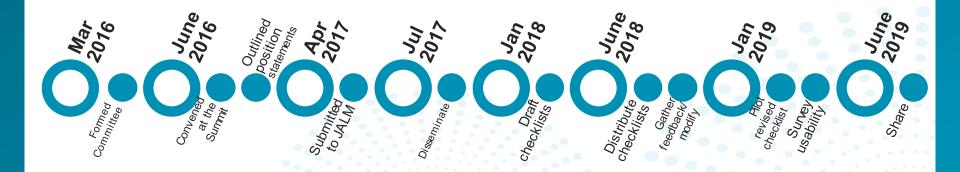


Dickerson, J.A.; Fletcher, A.H.; Procop, G.W.; et al. Transforming laboratory utilization review into laboratory stewardship: Guidelines by the PLUGS National Committee for Laboratory Stewardship. Journal of Applied Laboratory Medicine. 2017; 2(2): 259-268.

# **NCLS** Progress and Goals

- Gather feedback from published guidelines
- Create detailed checklists
- Pilot checklists









### We need you!

#### Laboratory Stewardship Checklist: Instructions

This checklist can be completed by one or several team members familiar with your institution's laboratory stewardship program. Prepare to spend 1-4 man hours completing the below checklist secause this checklist covers multiple disciplines, we recommend identifying a few key stakeholders to complete together. These stakeholders may include laboratory administrative director, laboratory medical director, laboratory stewardship committee clinicians, or informaticist. You may consider completing together or distributing the checklist among the key stakeholders to make sure different perspectives are captured.

#### Laboratory Stewardship Checklist: Governance

#### Leadership Commitment

A successful committee needs support from institutional and medical leadership. Individual leaders can provide this support by participating on the committee, appointing a chair/co-chair, or recommending members. Leadership support will also help determine the composition of the committee and the governance structure (i.e., the department that has ownership of the committee). It is recommended that the committee report back to both institutional and medical leadership on a regular basis to share success, as well as to request assistance for challenges.

- Does the institution have a dedicated hospital-wide committee geared towards the improvement of laboratory stewardship?
  - O Yes
- Does your facility have a formal, written statement of support from leadership (outside of Pathology/Laboratory Medicine) that encourages laboratory stewardship efforts?
  - Yes
  - O No
  - Under consideration.
- Does your facility receive any financial support from your institution for laboratory stewardship activities (e.g., support for salary, training, or IT support)?
  - O Yes
  - O No
  - No budget, but ancillary support provided

Step 1: Complete the checklist.

**Step 2**: Give feedback with usability survey.



https://redcap.iths.org/surveys/?s=TYNPMPPKPT



