Tales from the Trenches: Using Guidelines to Drive Insurance Coverage Policy

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Disclosures

- Employee and Shareholder, Concert
- Board Member and Shareholder, My Gene Counsel

Concert

is a software and managed services company that promotes health by providing the digital infrastructure for reliable and efficient management of advanced diagnostics and precision medicine

Digital infrastructure for advanced diagnostics

Essential infrastructure for effective & affordable precision medicine

Concert policies are guidelines -based and authored for clarity and automation

Clear & Comprehensive	• Written in clear language, free of technical jargon • Aimed to answer the question "Is this test covered?" • Comprehensively address the landscape of tests for which management is warranted
Evidence -Based	• Aligned with professional/ clinical guidelines wherever possible • Supported by primary literature, 3rd party tech assessments and FDA positions
Organized in Accordance with Market Practice	• Designed to apply to the service provided, including coverage of panels • Coverage algorithms correspond to a category of tests with the same clinical use • Policy Documents contain sets coverage algorithms with an area of testing
Designed for Usability	• Searchable from multiple entry points (test name, type, indication, billing code(s)) • Cross-references redirect when similar tests exist in different Policy Documents
Structured for Machine Readability	• Coverage algorithms linked to discrete fields (i.e. ICD, age, etc) where possible • Each test mapped to one coverage algorithm within a policy (by virtue of the test's category) • Each test mapped to relevant ICD and CPT codes • Policies are written to align with claim rules / edits

Concert publishes reference policy documents twice per year

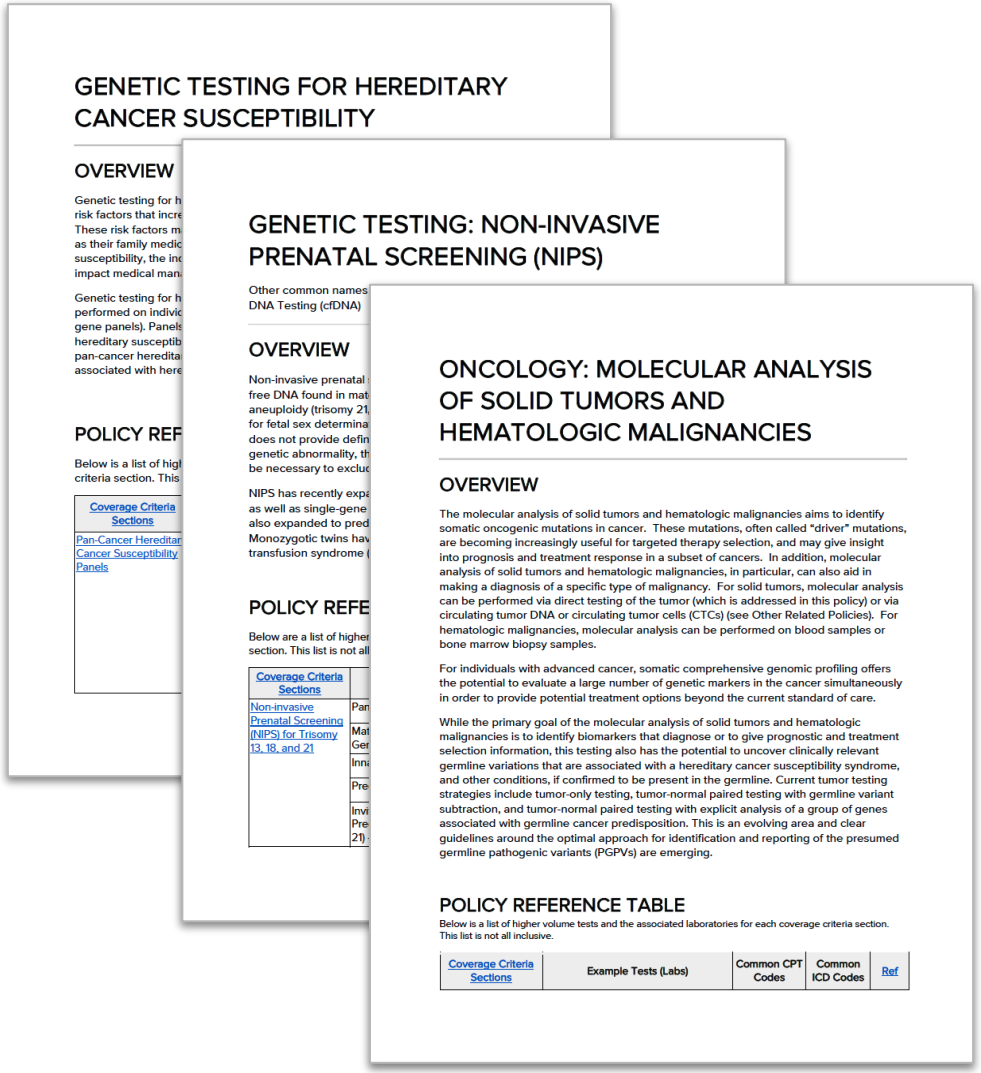
35+ Domain -based policy documents

Each policy document contains:

- Introduction
- Reference Table
- Other Related Policies
- Coverage Criteria (COAs) by type of test
- Notes and Definitions
- Background and References

For each policy there is a corresponding set of:

- Coding rules
- Claim edit s



Challenges in applying guidelines to payer coverage policy development

- Inconsistent, discrepant and vague language
- Unclear audience
- Choice of outcomes
- Timeliness

Inconsistent Language

NCCN Language	Concert B&R Language
Strongly recommend	NCCN recommends
Recommend	
Should offer	
Strongly consider	
Should be performed	
Must have XX test performed	
Necessary	
Recommends consideration	NCCN recommends consideration of
Is useful	
May be useful / used	
Clinicians may use this test	
Support the use of	
May facilitate	
Consider	
May be further defined	
Should be considered	
Can be considered	
Insufficient data	NCCN does not recommend
Does not recommend	
Not, as yet, mandated	
Do not provide clinically actionably prognostic information	
Evidence is not sufficient	
Unclear whether tests are reliably predictive	

Discrepant Language

ACMG 2010 Microarray guideline, reaffirmed in 2020:

Recommendations

1. CMA testing for CNV is recommended as a first-line test in the initial postnatal evaluation of individuals with the following:
   A. Multiple anomalies not specific to a well-delineated genetic syndrome.
   B. Apparently nonsyndromic DD/ID.
   C. Autism spectrum disorders.
2. Further determination of the use of CMA testing for the evaluation of the child with growth retardation, speech delay, and other less well-studied indications is recommended, particularly by prospective studies and aftermarket analysis.
3. Appropriate follow-up is recommended in cases of chromosome imbalance identified by CMA, to include cyto-

ACMG 2009 Short Stature guideline, reaffirmed with addendum in 2020:

would be indicated if Turner syndrome has been excluded.

b. Chromosomal microarray (comparative genomic hybridization [CGH] and/or single-nucleotide polymorphism [SNP]) should be part of the initial genetic work-up for idiopathic short stature (ISS) and small for gestational age (SGA) with persistent short stature as well as syndromic short stature, since the yield of pathogenic and likely pathogenic copy-number variants (CNV) was reported as high as 10% in this population in one study.[4] Multiple studies have reaffirmed use of microarray as first-line testing in patients with syndromic short stature with an average yield of 10–15%.[5–8] It is important to note that SNP-based

Vague Language

Genetics inMedicine

www.nature.com/gim

Check for updates

ACMG PRACTICE GUIDELINE

Exome and genome sequencing for pediatric patients with congenital anomalies or intellectual disability: an evidence-based clinical guideline of the American College of Medical Genetics and Genomics (ACMG)

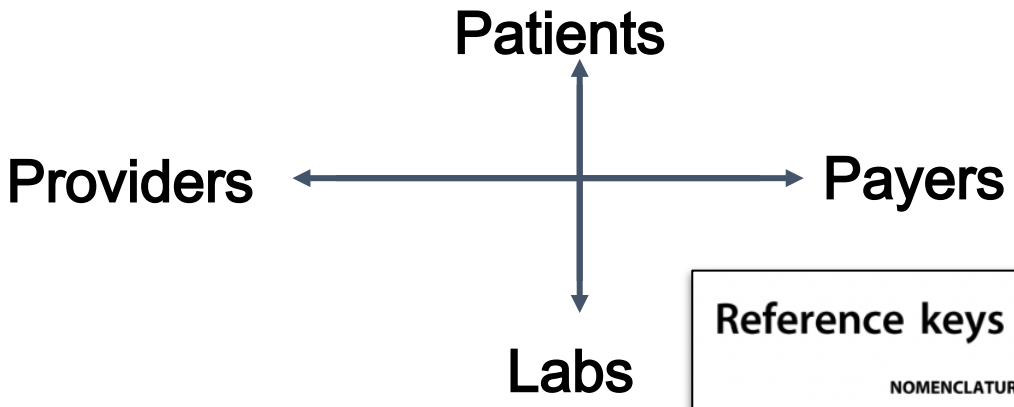
Kandamurugu Manickam[1,2], Monica R. McClain[3], Laurie A. Demmer[4], Sawona Biswas[5], Hutton M. Kearney[6], Jennifer Malinowski[7], Lauren J. Massingham[8,9], Danny Miller[10], Timothy W. Yu[11,12], Fuki M. Hisama[13] and ACMG Board of Directors[14]*

Recommendation

We strongly recommend ES and GS as a first-tier or second-tier test (guided by clinical judgment and often clinician–patient/family shared decision making after CMA or focused testing) for patients with one or more CAs prior to one year of age or for patients with DD/ID with onset prior to 18 years of age.

ANY?

Unclear audience



American Society of Hematology 2023 guidelines for management of venous thromboembolism:

Interpretation of strong and conditional recommendations

Implications for:	Strong recommendation	Conditional recommendation
Patients	Most individuals in this situation would want the recommended course of action, and only a small proportion would not.	Most individuals in this situation would want the suggested course of action, but many would not. Decision aids may be useful in helping patients to make decisions consistent with their individual risks, values, and preferences.
Clinicians	Most individuals should follow the recommended course of action. Formal decision aids are not likely to be needed to help individual patients make decisions consistent with their values and preferences.	Different choices will be appropriate for individual patients; clinicians must help each patient arrive at a management decision consistent with the patient's values and preferences. Decision aids may be useful in helping individuals to make decisions consistent with their individual risks, values, and preferences.
Policymakers	The recommendation can be adopted as policy in most situations. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator.	Policymaking will require substantial debate and involvement of various stakeholders. Performance measures should assess if decision making is appropriate.
Researchers	The recommendation is supported by credible research or other convincing judgments that make additional research unlikely to alter the recommendation. On occasion, a strong recommendation is based on low or very low certainty in the evidence. In such instances, further research may provide important information that alters the recommendations.	The recommendation is likely to be strengthened (for future updates or adaptation) by additional research. An evaluation of the conditions and criteria (and the related judgments, research evidence, and additional considerations) that determined the conditional (rather than strong) recommendation will help identify possible research gaps.

KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease:

Reference keys

NOMENCLATURE AND DESCRIPTION FOR RATING GUIDELINE RECOMMENDATIONS

Within each recommendation, the strength of recommendation is indicated as **Level 1** or **Level 2**, and the certainty of the supporting evidence is shown as **A**, **B**, **C**, or **D**.

Grade	Implications: Patients	Implications: Clinicians	Implications: Policy
Level 1 "We recommend"	Most people in your situation would want the recommended course of action, and only a small proportion would not.	Most patients should receive the recommended course of action.	The recommendation can be evaluated as a candidate for developing a policy or a performance measure.
Level 2 "We suggest"	The majority of people in your situation would want the recommended course of action, but many would not.	Different choices will be appropriate for different patients. Each patient needs help to arrive at a management decision consistent with their values and preferences.	The recommendation is likely to require substantial debate and involvement of stakeholders before policy can be determined.

Grade	Certainty of evidence	Meaning
A	High	We are confident that the true effect is close to the estimate of the effect.
B	Moderate	The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
C	Low	The true effect may be substantially different from the estimate of the effect.
D	Very low	The estimate of effect is very uncertain, and often, it will be far from the true effect.

Practice points are consensus-based statements representing the expert judgment of the Work Group and are not graded. They are issued when a clinical question did not have a systematic review performed, to help readers implement the guidance from graded recommendation (e.g., frequency of monitoring, provision of standard care [such as regular clinic visits], referral to specialist care, etc.), or for issuing "good practice statements" when the alternative is considered to be absurd. Users should consider the practice point as expert guidance and use it as they see fit to inform the care of patients. Although these statements are developed based on a different methodology, they should not be seen as "less important" or a "downgrade" from graded recommendations.

Choice of Outcomes

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PRACTICE GUIDELINE

Genetic testing and counseling for the unexplained epilepsies: An evidence-based practice guideline of the National Society of Genetic Counselors

Lacey Smith[1] | Jennifer Malinowski[2] | Sophia Ceulemans[3] | Katlin Peck[4] | Nephi Walton[5] | Beth Rosen Sheidley[1] | Natalie Lippa[6]

Recommendation 1: We strongly recommend that individuals with unexplained epilepsy be offered genetic testing, without limitation of age.

a. We strongly recommend comprehensive, multi-gene testing, such as ES/GS or MGP as a first-tier test. We conditionally recommend ES/GS over MGP as the first-tier test.

b. The MGP panel should have a minimum of 25 genes and include copy number analysis.

2.3 | Data synthesis and assessing the certainty of the evidence

From 5985 articles screened, 154 were included in random-effects meta-analyses of diagnostic yield, and 43 further provided evidence of clinical utility and were narratively synthesized (Sheidley et al., 2022). The evidence from the SER was provided to the guideline workgroup for review. For each outcome, certainty of the evidence was based on the overall risk of bias of included studies, heterogeneity (inconsistency), indirectness, and imprecision of the results and reported as either high, moderate, low or very low.

Diagnosis can be an insufficient outcome

Timeliness

Too Fast ⟷ Too Slow

NEVER…

Non-Small Cell Lung Cancer

Guidelines

NCCN Guidelines Version 11.2024

- Non-Small Cell Lung Cancer

11!

American Thoracic Society Documents

American Thoracic Society/European Respiratory Society Statement: Standards for the Diagnosis and Management of Individuals with Alpha-1 Antitrypsin Deficiency

This Joint Statement of the American Thoracic Society and the European Respiratory Society was approved by the ATS Board of Directors, December 2002, and by the ERS Executive Committee, February 2003

Summary and Recommendations

Problem	Recommendations for Maximum Impact
Inconsistent language	• Develop and implement recommendation standard language • Reconcile discrepancies (within/across) organizations if possible via guideline updates and addenda • Clinical observations cited within guidelines should be objectively definable wherever possible
Unclear Audience	• Consider the different audiences of guidelines and clarify language for those audiences
Proximal Outcomes	• Choose the most clinically impactful outcomes available and, where necessary, chain evidence to tie diagnosis to clinical impact
Challenging Update frequencies	• Frequent updates (>2x/year) to guidelines pose implementation challenges • Outdated guidelines should be updated, retired or reaffirmed (w/ addenda if necessary)

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