

# Commercial Test Coverage

*Learn how payers' think...if you dare*

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Lon Castle, MD

Associate Chief Medical Officer, Precision Medicine

**EviCore**  
By EVERNORTH

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# Disclosure

Employee of EviCore healthcare, a health-services company wholly owned by Cigna

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# Agenda

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**Understanding how payers evaluate tests**



**What evidence do payers look for**



**Establishing medical policy coverage expectations**



**Summary**

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# How Payers Evaluate Evidence

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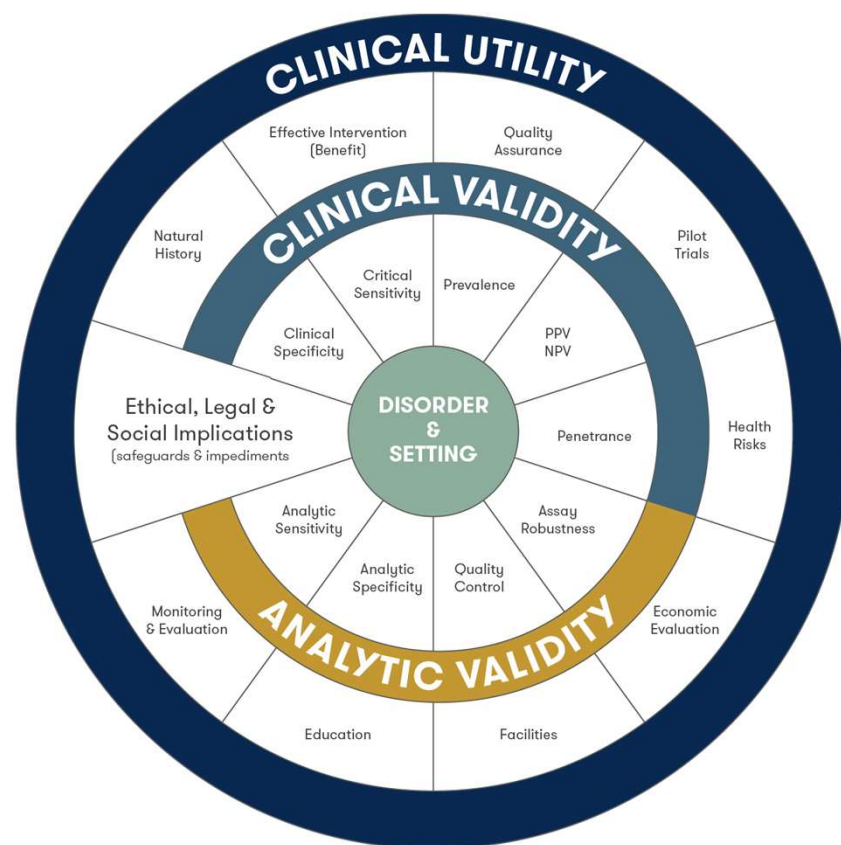
# Evaluating New Molecular Diagnostic & Genomic Tests

## + Assess scientific evidence using the ACCE model<sup>1</sup>

- Developed by the Centers for Disease Control and Prevention (CDC) Office of Public Health Genomics
- Became the standard framework for evaluating scientific data on new genetic tests

## + Evaluation of Genomic Applications in Practice and Prevention (EGAPP)

- Developed using ACCE framework
- **Goal:** establish and evaluate an evidence-based method for assessing genetic tests and other types of genomic technology as they transition from the research arena to the practice arena



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<sup>1</sup>CDC: ACCE: A CDC-sponsored project (2000–2004). Available at: [http://www.cdc.gov/genomics/gtesting/ACCE/acce\\_proj.htm](http://www.cdc.gov/genomics/gtesting/ACCE/acce_proj.htm) - T1.

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# Payer Policy Coverage Process

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## Interesting, but...

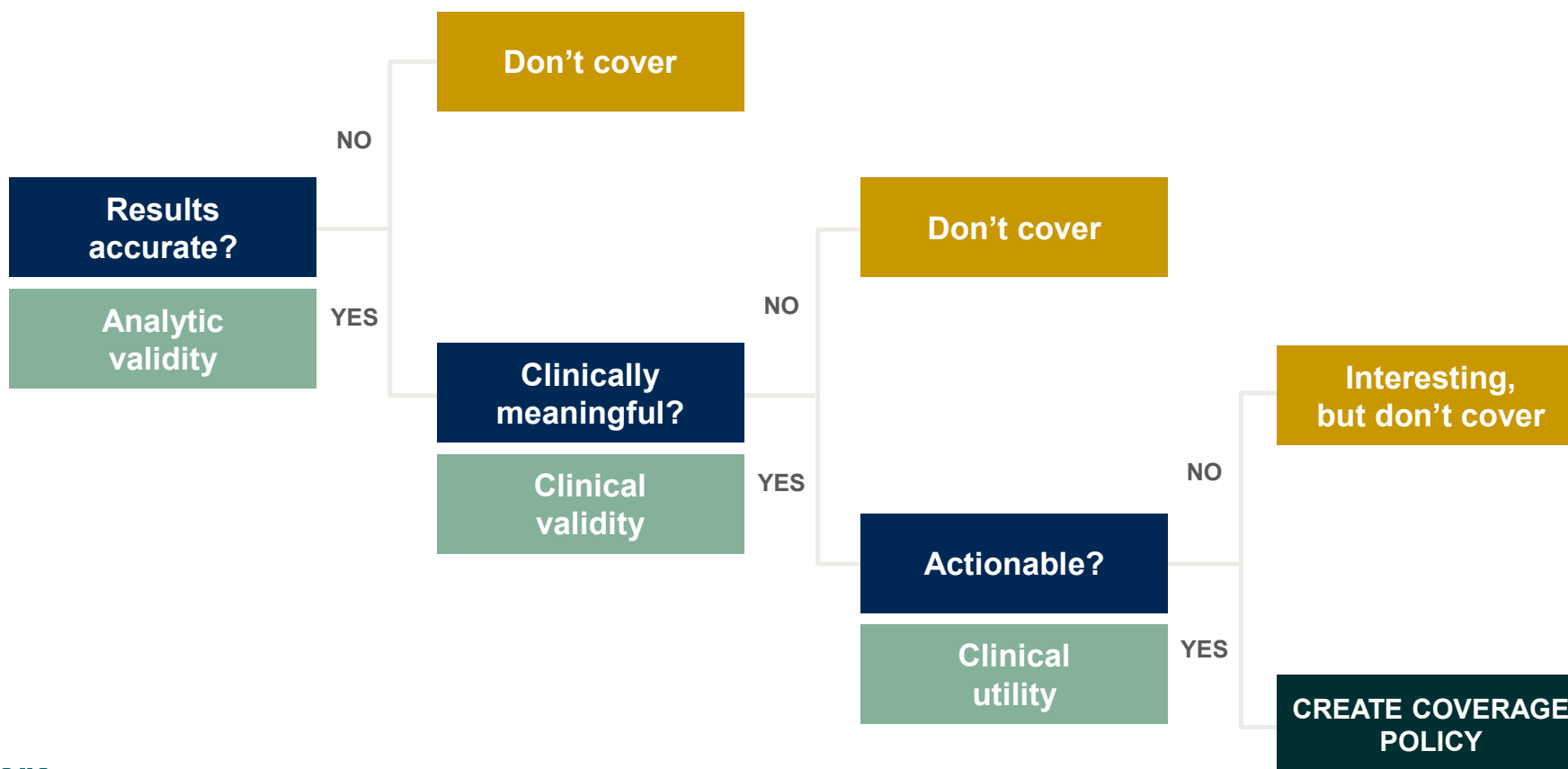
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**A genetic mutation in the OPN1SW gene is responsible  
for blue-yellow color blindness**

# Payer Policy Coverage Process

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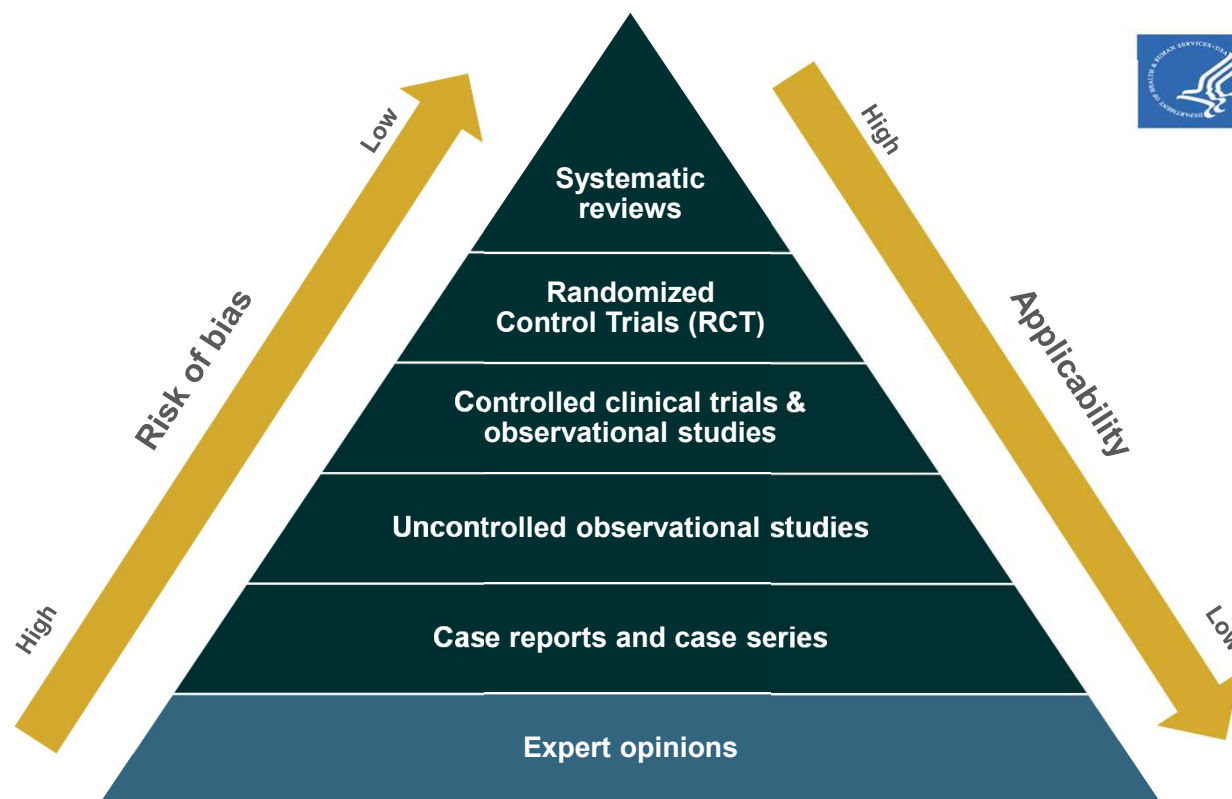
# Why Payers Require Clinical Utility Studies

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## Clinical validity publications alone do not warrant coverage

- + Test rapidly identified infectious organisms and performs antibiotic sensitivity testing (AST) through a novel process
- + Published eight clinical validity trials on the sensitivity, specificity, PPV, and NPV
  - Compared with current testing methods, significantly reduced times to identify organisms and perform AST
- + Performed comparative effectiveness trials, evaluating concordance of their results with those of competitors and traditional organism-identification methods
  - Test showed diagnostic accuracy similar to traditional identification methods
  - It did not perform as well in certain organisms or with polymicrobial infections
- + Clinical utility trial confirmed the analytical validity findings, significantly reducing the time to identify organisms and perform AST<sup>1</sup>
  - However, improvement in organism identification and speed-to-therapy time did not reduce antimicrobial therapy use or improve clinical outcomes significantly

# Payers Follow a Publication Hierarchy for Evidence Reviews



# External Sources in Evidence Assessment

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## Other external sources of data evaluated

- + Guidelines or pathway organizations (e.g. NCCN, AHA)
- + Technology Assessment Committees (e.g. Hayes, Evidence Street, ECRI)
- + Regulatory and other governmental agencies (e.g. CMS, MAC, FDA, CLIA)
- + Professional societies (e.g. CAP, AMP, ASCO, ACC)
- + Individually contracted providers and industry experts
- + Competitor medical policies



# At the End of the Day, It's All About Clinical Utility

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The bar has not changed

**Must establish clinical utility and value**

- + Just detecting surrogate endpoints (such as antibiotic resistance and speed-to-therapy) does not show clinical utility; need to demonstrate the test can **improve patient outcomes**

**“There’s a really high bar to show survival benefits. These large, randomized studies need to prove not just that more cancers were diagnosed in patients who got a screening test but that the health and survival of the entire group was better as a result of being screened.”<sup>1</sup>**

**— Maximilian Diehn, MD, PhD; Professor, Radiation Oncology, Stanford University**

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<sup>1</sup>Madhusoodanan J. *Chemical & Engineering News*. 2019;97(47):18-23.

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# Summary

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**Payers follow very specific evidence evaluation processes**



**Proving clinical utility requires improved health outcomes**



**The type and quality of publications matters**



**Set expectations with your company's leadership**

# Thank You

