Standardizing Medical Coverage Policies for Laboratory Tests: PLUGS Recommendations for Best Practices, Draft

3/24/2025

Authors: PLUGS Insurance Alignment Committee, Medical Necessity Working Group

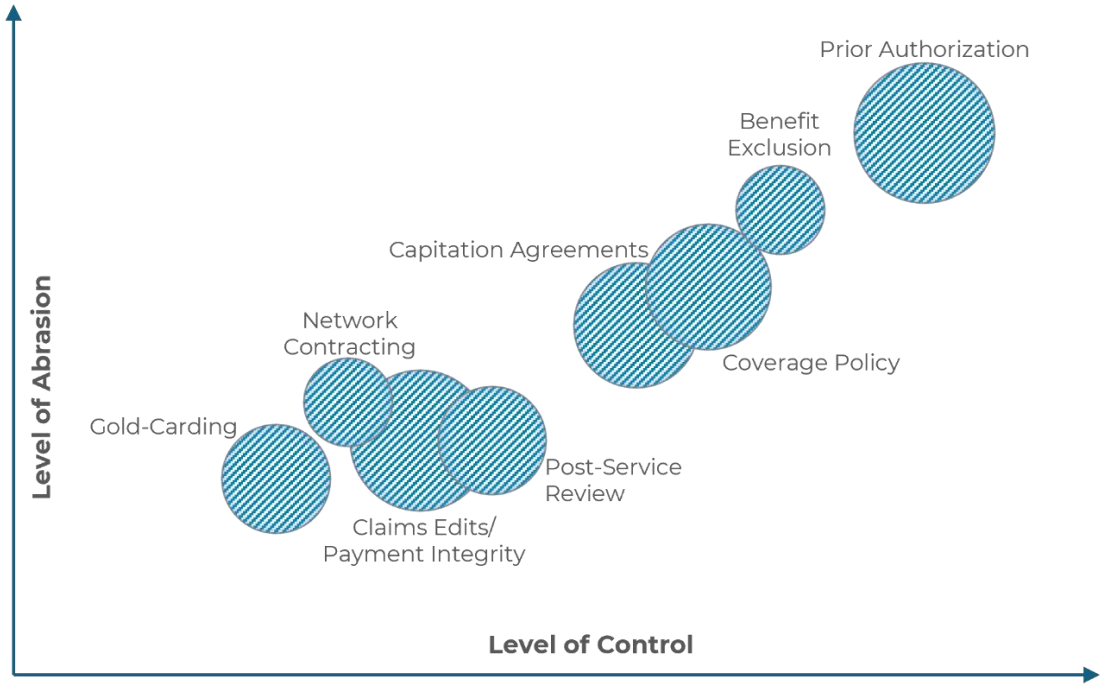
Corresponding Author: Julie Wiedower PhD, MS, CGC: jkaylor@guardanthealth.com

Goal: To present ideas that increase standardization, functionality, and transparency of medical coverage policies for laboratory testing.

Background:

Health insurance companies use various approaches to manage healthcare services to control costs, ensure quality care, and provide value to their policyholders. Management of services may vary in terms of scope, costs to administer, abrasion, and efficacy in addressing healthcare services.

Figure 1: Ways of Managing Healthcare Services According to Level of Control Expressed by Health Insurance Companies and Level of Abrasion with Members and Provider Network.



Management through Coverage Policies

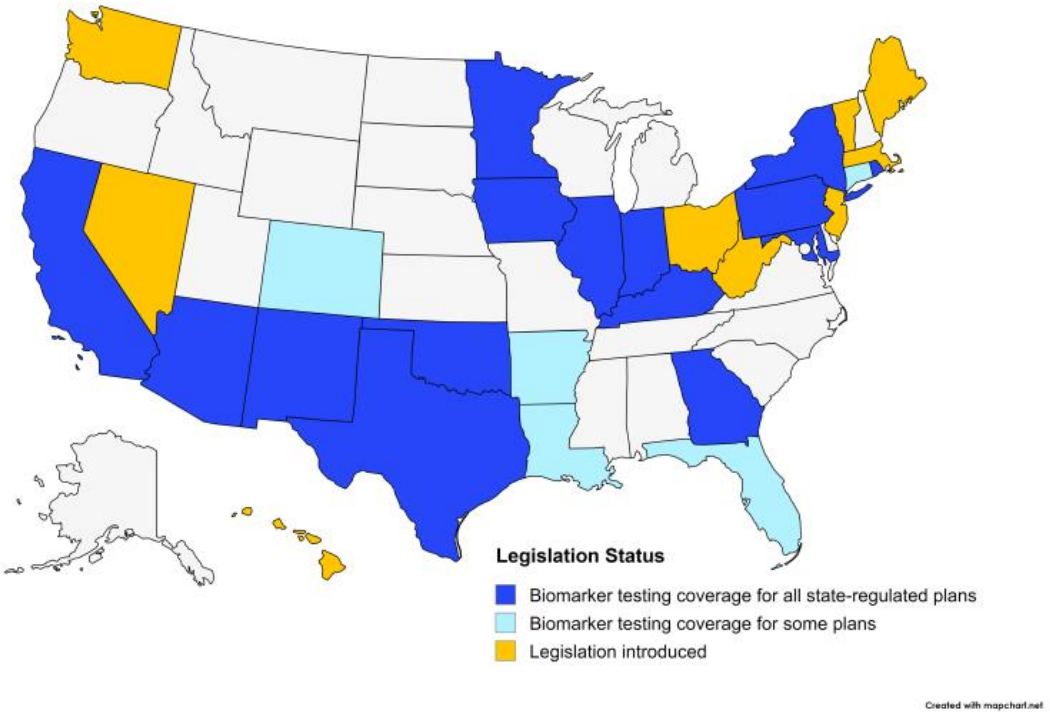
Payers establish medical coverage policies to outline the scope of services covered under a particular insurance plan. These policies define what treatments, procedures, and medications are eligible for reimbursement. By setting clear and transparent guidelines, insurance companies can manage costs and ensure that policyholders receive appropriate and necessary care.

Evidence review frameworks have been created to assist medical coverage decision-making and policy writing and may be utilized across medical disciplines[1–3]. Several laboratory testing-specific technology assessments and frameworks exists such as those performed by regulatory agencies such as AHRQ, CAP, CLIA and FDA, which often consider elements of population, intervention, comparator, outcomes, and levels of evidentiary support. There are also evidence frameworks for those writing policy or technology assessments such as Evaluation of Genomic Applications in Practice and Prevention (EGAPP) for genomic testing services[4–6]. Centers for Medicaid and Medicare Services MolDx program has a technical assessment process in which the AACE (Analytical validity, clinical validity, clinical utility, and ethical, legal, social implications) criteria are applied to testing under review[7,8]. Commercial coverage policies rarely cite the frameworks used.

There are several challenges with the equitable and effective application of laboratory testing coverage policies. For example, there is a notable lack of standardization among policies regarding their formats, accessibility by providers and patients, terminology, evidence used, coding and coverage stances[9]. Even when national guidelines exist, medical coverage policies vary greatly, with 80% of policies for genomic testing included in NCCN guidelines having more restrictive criteria than outlined within guidelines[10]. Furthermore, insurance coverage criteria have been shown in some circumstances not to differentiate between patients who benefit from genetic testing and those who do not[11].

In response to widely varied coverage among insurance plans, state legislatures have enacted laws which address coverage for certain laboratory services such as prostate cancer screening (PSA), rapid whole genome sequencing in critically ill infants, and biomarker testing for advanced cancer treatment selection. State legislation, however, may be enforced at the discretion of the state insurance commissioner and any disagreement in interpretations of legislative language are likely to lead to litigation. The legislative mandate for coverage is also state dependent and limited to certain kinds of payers outlined in the statutes, leaving gaps in coverage across state lines. Rather than a piecemeal approach of state legislation, a far more elegant approach would be standardization of insurance coverage policies.

Figure 2: Biomarker Testing Legislation Across the United States (American Cancer Society Cancer Action Network).



Best Practice Standardized Elements for Coverage Policies:

The standardization of coverage policies for laboratory testing is consistent with the goals of payers, providers, laboratories, and patients. PLUGS (Patient-Centered Laboratory Utilization Guidance Services) is a multi-stakeholder laboratory stewardship collaboration whose mission is to improve test access, ordering, retrieval, interpretation, and reimbursement. A main initiative of PLUGS is insurance alignment, with efforts focused on the appropriate, equitable administration of healthcare services originating in the laboratory. The PLUGS Insurance Alignment Committee drafted consensus recommendations which were subsequently presented to stakeholders for feedback and verification.

Policies which contain the standardized policy elements outlined in Table 1, and sample language in Table 2, may be more efficiently used by payer staff, providers, laboratories, and patients.

Table 1: Recommended Standardized Policy Elements with Rationale.

Policy Element	Rationale
Plain Language Summary	Ordering providers, prior authorization staff, and health plan reviewers often need to apply a medical policy which lies outside their area of expertise or clinical training. A Plain Language Summary provides maximum opportunity for application and serves the goal of increased transparency to all the health plan network and members.
Coverage Stance	Standard in policies and aids in rapid adjudication
Medical Necessity Criteria	Plainly describe the clinical circumstances for which the test is medically necessary. Specific clinical criterion should be collected and available in routine clinical documentation and ideally associated with diagnosis coding.
Description of Test and Technology	Because some testing may be performed with different methodologies, the policy should identify which methods are obsolete or do not have sufficient evidence to meet medical necessity criteria. For tests in which some specimen types meet medical necessity criteria and some do not, the policy should clearly state the specimen requirements.
Evidence and Rationale for coverage	Level of evidence reviewed is discussed and the level of evidence supporting coverage decision is equivalent to levels of comparably covered services. When conflicting with professional guidelines, higher level evidence should be presented.
Methodology of Evidence Review	Evidence summaries should follow best practices for systematic literature reviews, including search methodology. Evidence is assessed via a clearly defined, preferably a published, validated schema such as AHRQ.[12]
Diagnosis Codes	Because non-clinical staff and automated systems are increasingly common in review and billing processes, listing, and annotating diagnosis codes with medical necessity criteria is an effective measure to ensure

	sufficient, correct clinical information is provided to the health plan.
CPT Codes	Because many policies may include language which applies to a category of tests or technologies, specifying CPT codes considered medically necessary when criteria are met or experimental/investigational is helpful in adjudication and policy maintenance. Coding may allow for a health plan to evaluate specific tests which have evidence, and designate tests without evidence as Experimental/ Investigational.
Updates, Cycle and Transparency	Because evidence in different areas of medicine is evolving at different rates, the inclusion of the relevant dates of each review and update is foundational to understanding the relevance of the policy.

Considerations for Standardized Policy Elements:

Plain language summary should state if the test is ever useful (Medically Necessary or Experimental/Investigational/Never Medically Necessary), include a brief summary of the most notable criteria and associated diagnosis codes, what limitations apply, and where codes and details can be found in the policy. *The coverage stance* should be featured clearly and toward the beginning of the policy to allow for rapid identification of necessary information for ordering providers and adjudication.

When *medical necessity criteria* are included, criteria should consist of clinical information routinely documented in standard clinical practice for the indication. A criterion which is not routinely available in clinical documentation or within a test requisition form is likely to require manual review and burdensome outreach to the health care provider. Medical necessity criteria should also not contribute to inequities in access or care. A requirement for in-person, invasive, or time-consuming services may reduce compliance and introduce inequities for patients with limited resources of time, support systems, or finances. Ethnic or ancestral criteria for coverage has been challenged in the areas of reproductive carrier screening, among others[13]. If utilization trends establish low compliance with guideline-recommended care, medical necessity criteria which are restrictive may aggravate the issue of underutilization by placing barriers to access.

A brief *description of the technology or testing* or methods for which coverage policy applies may assist users in identifying the correct policies for the indication and

testing in question. In genetics, with over 150,000 genomic tests on the market, a comprehensive list is often infeasible, but a description of test classes can be included, such as multi-gene next-generation sequencing panels. Outside of genetics it is sometimes helpful to briefly list the relevant covered technologies such as **mass spectrometry** or automated enzyme immunoassay. As is standard with scientific literature, the *methodology of evidence review* should be included in medical policies. Many frameworks for evidence evaluation exist, and adherence to a validated framework should be standard for health plan coverage policies, given the scope and impact of these documents in healthcare decision making. Methodologies for systematic literature reviews, such as PRISMA, should not only be utilized for coverage determinations but should be transparently documented. This may include dates of literature searches, sources searched, and search terms used, at a minimum. Such rigor ensures that stakeholders may engage with the health plan when key evidence is not reviewed or discussed. To produce the highest quality coverage policies, payers should adhere to the standards for literature review and documentation.

The *evidence and rationale* supporting a coverage policy determination should provide the hierarchy and categorization of evidence. If citing a particular evidence hierarchy schema, such as the Evidence Based Medicine Pyramid, notation of evidentiary support warranting coverage can be very helpful[14]. As evidence is reviewed, it should be synthesized into coverage rationale, so that the reader may see a clear path from evidence to coverage. For example, if including drawbacks or limitations of one test or set of studies, a plan should summarize how the limitations are outweighed by evidence of benefit justifying a decision to cover testing. Conversely, if a test is not covered, there should be evidence at the same level or higher demonstrating limitations or risks that outweigh the evidence demonstrating benefit. If a coverage policy departs from national guidelines, then the rationale should describe how evidence meeting a higher standard supports departure. Summaries of key evidence should include a discussion of the population, methodology and limitations. Most importantly, the literature review methodology should be documented for each iteration, so that a comprehensive review of evidence can be demonstrated to the reader. While the approach to the literature review and categorizing evidence should be systematic, it is not the case that every test in every medical domain meet the same threshold of scientific evidence to achieve coverage. The threshold for medical necessity should be the standard of care, which is commonly defined as the expectation of the average provider to diagnose, treat, monitor, and communicate about a health condition. For common chronic diseases, the standard of care is often based on strong evidence. However, the standard of care may be based on weaker evidence as is often the case for patients with inherited diseases with severe phenotypes; patients with multiple diseases and comorbidities; or complex patients with multi-symptom syndromes as can occur in autoimmune or inflammatory diseases.

Elements such as *diagnosis and procedure codes* streamline the application of coverage policies. Code-based algorithms and claims edits are one way in which a policy may be codified to increase automation. Criteria which correspond to diagnosis codes listed allow providers to be mindful of coding practices and clinical information provided as well as reduce the review burden of health plan personnel. Code-based rules enable post-service audits and may identify areas of high and low risk so that other management modalities may be explored. Finally, the *policy update documentation and review cycle* should be noted for transparency and stakeholder engagement. This allows the stakeholders to address any gaps in evidence reviewed or more conveniently submit or publish evidence in a timely manner for health plan consideration.

Increased standardization of medical coverage policies for laboratory testing is needed and has the potential to reduce burden and abrasion significantly. Adoption of the Best Practices for Coverage Policies is encouraged to enhance the equity, access, and quality of care as well as streamline many healthcare processes associated with laboratory testing, billing, and payment.

Table 2: Example Language for Standardized Policy Elements. These are composite teaching examples based on elements the authors have observed in payer and government policies.

Policy Element	**Examples**
Plain Language Summary	"Whole exome sequencing is considered medically necessary in some clinical circumstances including multi-system disease or acutely ill infants. This testing is not medically necessary in healthy individuals or when a known condition is strongly suspected. See specific criteria below and associated codes for testing and diagnoses."
Coverage Stance	"Allergen-specific IgG allergy (CPT code 86001) is considered never medically necessary/experimental/investigational in all clinical circumstances." "Testing for HFE variants for hemochromatosis is considered medically necessary when an individual has a fasting transferrin saturation 45% or higher or an elevated serum ferritin or a first degree relative diagnosed with the condition"

Medical Necessity Criteria, ICD-10 codes, CPT codes *	"Protein electrophoretic fractionation and quantitation of serum (CPT code 84165) is considered medically necessary in the evaluation of individuals suspected of having a plasma cell dyscrasia, including multiple myeloma. It is also indicated in the monitoring of patients known to have a plasma cell dyscrasia. The extensive list of ICD-10 codes associated with individuals presenting with signs and symptoms of plasma cell dyscrasias are shown in the ICD-10 table. Similarly, the list of ICD-10 codes associated with the plasma cell dyscrasias are shown in the ICD-10 table." "Procalcitonin (CPT code 84145) testing may be considered medically necessary in patients with lower respiratory tract infections (e.g. J22, J18, J21.9, J20.9)."
Description of Test and Technology	• "Comprehensive genomic profiling next generation sequencing panels [technology] performed on tissue or plasma [specimens] are considered medically necessary for patients with advanced solid cancers who are candidates for an FDA-approved therapy. " • "Bleeding Time (CPT code 85002) is obsolete and is considered never medically necessary."
Evidence and Rationale for coverage	"While case reports show circulating tumor DNA for minimal residual disease may identify patients who are at high risk of cancer recurrence, high level evidence, such as systematic reviews and prospective clinical studies with large cohorts, demonstrate that this class of testing does not impact cancer mortality or morbidity. Additionally, national guidelines consider the evidence insufficient for routine clinical practice." "Based on longstanding classification criteria from the American College of Rheumatology, the Antinuclear Antibody Test (CPT code 86038) is included in the

	evaluation of individuals suspected of having systemic lupus erythematosus."
Methodology of Evidence Review	"Literature Review conducted in PubMed 01/01/24, with keywords "Proclarix AND Prostate Cancer". This produced 30 publications of which 20 addressed the relevant PICO. These were further analyzed."
Updates, Cycle and Transparency	Vitamin D testing: Last Review 3/1/2024 Effective 4/15/2005 Next Review 3/1/2025
*Notes: The examples are composite teaching statements, which are supposed to represent excerpts from a hypothetical policy, rather than quotes from an existing policy. ICD-10 coding tables tend to be long. ICD-10 codes for the evaluation for the presence of a disease are based on cross-walking the most common signs, symptoms, and associated health conditions into the ICD-10 coding system. Specific syndromes and diseases also have ICD-10 codes, which are used to support testing for monitoring the syndrome or disease.	

References:

1. Huang X, Lin J, Demner-Fushman D. Evaluation of PICO as a Knowledge Representation for Clinical Questions. *AMIA Annu Symp Proc*. 2006;2006:359-363.

2. Eriksen MB, Frandsen TF. The impact of patient, intervention, comparison, outcome (PICO) as a search strategy tool on literature search quality: a systematic review. *J Med Libr Assoc JMLA*. 2018;106(4):420-431. doi:10.5195/jmla.2018.345

3. Value Assessment Framework. ICER. Accessed October 14, 2023. https://icer.org/our-approach/methods-process/value-assessment-framework/

4. Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group. The EGAPP initiative: lessons learned. *Genet Med*. 2014;16(3):217-224. doi:10.1038/gim.2013.110

5. Teutsch SM, Bradley LA, Palomaki GE, et al. The Evaluation of Genomic Applications in Practice and Prevention (EGAPP) initiative: methods of the EGAPP Working Group. *Genet Med*. 2009;11(1):3-14.

6. Agency for Healthcare Research and Quality (AHRQ). Accessed June 7, 2024. https://www.ahrq.gov/

7. ACCE Model Process for Evaluating Genetic Tests | CDC. Published September 27, 2021. Accessed October 2, 2021. https://www.cdc.gov/genomics/gtesting/acce/index.htm

8. MolDX - Technical Assessment. Accessed April 17, 2024. https://www.palmettogba.com/palmetto/moldxv2.nsf/DID/9W2LPH1487

9. Chambers JD, Saret CJ, Anderson JE, Deverka PA, Douglas MP, Phillips KA. EXAMINING EVIDENCE IN U.S. PAYER COVERAGE POLICIES FOR MULTI-GENE PANELS AND SEQUENCING TESTS. *Int J Technol Assess Health Care*. 2017;33(4):534-540. doi:10.1017/S0266462317000903

10. Wong WB, Anina D, Lin CW, Adams DV. Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors. *Pers Med*. 2022;19(3):171-180. doi:10.2217/pme-2021-0174

11. Amendola LM, Hart MR, Bennett RL, et al. Insurance coverage does not predict outcomes of genetic testing: The search for meaning in payer decisions for germline cancer tests. *J Genet Couns*. 2019;28(6):1208-1213. doi:10.1002/jgc4.1155

12. Methods Guide for Medical Test Review. Published online 2012. Accessed June 7, 2024. https://www.ncbi.nlm.nih.gov/books/NBK98241

13. Kaseniit KE, Haque IS, Goldberg JD, Shulman LP, Muzzey D. Genetic ancestry analysis on >93,000 individuals undergoing expanded carrier screening reveals limitations of ethnicity-based medical guidelines. *Genet Med Off J Am Coll Med Genet*. 2020;22(10):1694-1702. doi:10.1038/s41436-020-0869-3

14. Swanson JA, Schmitz D, Chung KC. How to Practice Evidence-Based Medicine. *Plast Reconstr Surg*. 2010;126(1):286-294. doi:10.1097/PRS.0b013e3181dc54ee