Laboratory Testing Services

MEDICAL POLICY NUMBER: 455

Effective Date: 6/1/2026

Last Review Date: 3/2026

Next Annual Review: 3/2027

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

I. A laboratory test or panel required to prevent, evaluate, diagnose, or treat an illness, injury, disease, or its symptoms may be considered **medically necessary** when all of the following are met (A.-G.):

   A. Analytical validity is established (i.e. accuracy, precision, sensitivity, specificity, and reproducibility) based on published, peer reviewed evidence; and
   B. The test is ordered and performed according to the manufacturer's intended indications for use, by a qualified health care practitioner acting within scope and actively managing the member's care; and
   C. The test is FDA cleared/approved and/or performed in a CLIA-credentialed laboratory appropriate to the method; and
   D. The test is not primarily for convenience; and
   E. The test type, frequency, extent, site, and duration are appropriate for the member's condition; and
   F. The test is not duplicative of other services previously or currently performed for the same clinical purpose; and
   G. Any one of the following criteria is met (1.-3.):
      1. The USPSTF assigns a Grade A or B recommendation for the intended use; or
      2. There is evidence based professional society guidance supporting use of the test for the member's indication; or
      3. Sufficient published evidence demonstrates the test changes clinical decision making and improves health outcomes for the member.

II. A laboratory test is considered **not medically necessary** when criterion I. above is not met, including but not limited to any of the following (A.-F.):

A. Criterion I. above is not met, including lack of analytical validity, inappropriate frequency, or duplication of prior testing without documented clinical change**; or**
B. Screening in asymptomatic individuals without USPSTF Grade A/B recommendation (see Policy Guidelines), or specific preventive benefit coverage; **or**
C. Results will not directly impact clinical management (e.g., tests whose results would not alter treatment or diagnostic decisions); **or**
D. Self referred/member initiated testing not ordered under the direction of a qualified practitioner; **or**
E. The test is "non- standard" (see Policy Guidelines), such as using non-standard methodology or specimen type, incorporating broad multi analyte panels of low/uncertain clinical utility, or reporting in non-recognized units; **or**
F. There is insufficient peer reviewed evidence to demonstrate safety, effectiveness, or improvement in net health outcomes for any indication; absence of FDA authorization for the intended use.

Link to Evidence Summary

POLICY CROSS REFERENCES

- Definition of Investigational, MP5
- Definition of Medically Necessary, MP38
- Genetic and Molecular Testing, MP215
- New and Emerging Technologies and Other Non-Covered Service, MP23
- Non-Covered Genetic Panel Tests, MP213

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request. Medical records to include documentation of all of the following:

- All medical records and chart notes pertinent to the request. This includes:
  - History
  - Physical examination
  - Treatment plan

DEFINITIONS

Standard vs. Non-Standard Laboratory Tests

- **Standard test/panel:** Performed in a CLIA-certified clinical laboratory and recognized as clinically valid by relevant organizations (e.g., CAP, ASCP, AMP, CLSI).
- **Non-standard test:** Fails the above, uses non-standard methodology/specimen, contains large low-utility analyte panels, or reports in non-recognized units; such tests are not medically necessary.

BACKGROUND

Screening Laboratory Tests

Screening laboratory tests are performed to detect a disease or risk factor in individuals who do not have symptoms. This is distinct from diagnostic testing, which is performed to evaluate a condition in individuals who already have signs, symptoms, or an established clinical concern. Screening tests can improve health outcomes when early detection enables effective interventions, risk-factor modification, or monitoring that reduces morbidity or mortality. However, many laboratory tests lack sufficient evidence to support their use as screening tools.

For a screening laboratory test to be considered clinically useful, it should generally meet the following characteristics:

- The condition being screened for is sufficiently prevalent in the population being tested and associated with significant morbidity or mortality.
- Early identification and treatment before symptom onset are shown to reduce morbidity and/or mortality.
- The test demonstrates adequate sensitivity and specificity, with a low likelihood of false positives and false negatives.
- The test is safe, accessible, and feasible to administer.
- Effective treatment or preventive interventions exist for individuals identified through screening.

U.S. Preventive Services Task Force (USPSTF)

The U.S. Preventive Services Task Force (USPSTF) provides authoritative, evidence-based recommendations for screening services, including screening laboratory tests. Screening laboratory tests are considered medically necessary only when they carry a USPSTF Grade A or B recommendation for the specific population and indication. Examples of laboratory-related USPSTF A/B recommendations include:

- Screening for hepatitis B infection in adolescents and adults at increased risk
- Screening for prediabetes and type 2 diabetes in adults aged 35–70 years with overweight or obesity
- Rh(D) blood typing and antibody screening in pregnant individuals at the first prenatal visit
- Screening for colorectal cancer in adults aged 45–49 years

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

Due to the large and extensive body of evidence surrounding laboratory testing, the evidence supporting the policy criteria was limited to relevant clinical practice guideline recommendations. Below is a summary of available guidelines identified through February 2026.

CLINICAL PRACTICE GUIDELINES

College of American Pathologists (CAP)

Evidence from CAP-led quality studies shows that overuse of laboratory testing contributes significantly to unnecessary clinical cascades, including additional imaging, specialist referrals, and invasive procedures.[1-3] CAP has emphasized that a notable proportion of routine inpatient and outpatient laboratory orders provide minimal diagnostic value when applied broadly, especially in low-risk or asymptomatic populations. CAP's diagnostic stewardship initiatives highlight that inappropriate initial testing is one of the strongest drivers of downstream utilization, with false positives frequently leading to redundant or avoidable follow-up testing. Programs evaluated through CAP's Q-Probes and Q-Tracks have demonstrated that implementing structured laboratory-ordering guidance reduces unnecessary tests while maintaining or improving clinical outcomes. These findings support restricting testing to clinically justified scenarios and align with the principle that laboratory services should meaningfully contribute to diagnosis or management rather than serve as default or routine evaluations.

Clinical and Laboratory Standards Institute (CLSI)

CLSI publishes rigorous standards outlining the characteristics a laboratory test must meet to demonstrate acceptable analytical validity.[4,5] These standards consistently show that tests lacking validated accuracy, precision, sensitivity, specificity, and reproducibility may generate misleading results that compromise clinical decision-making. CLSI evaluations indicate that non-standard or unvalidated methods exhibit higher variability and error rates compared with established, guideline-endorsed methods. Evidence across multiple CLSI method-comparison studies demonstrates that improper calibration, non-standard specimen types, and unvalidated analytic platforms are associated with increased false-positive and false-negative rates. Such errors may lead to inappropriate diagnoses, missed conditions, or unwarranted treatment initiation. CLSI's body of work strongly supports requiring established analytical validity before a test is considered medically necessary, reinforcing that patient-care decisions should rely only on tests that meet recognized performance standards.

American Association for Clinical Chemistry (AACC)

Evidence summarized in AACC guidance documents underscores the importance of clinical utility as a prerequisite for ordering and reimbursing laboratory testing.[6,7] AACC reviews highlight that even analytically sound tests may have limited value when ordered in scenarios where results do not alter clinical decisions. Studies evaluated by AACC demonstrate that low-utility testing often leads to false reassurance, false alarms, and additional work-ups that do not improve health outcomes. Conversely, tests with demonstrated clinical utility—such as those used for treatment selection, toxicity monitoring, or precise diagnosis—are associated with clearer pathways to improved patient outcomes. AACC has repeatedly emphasized that clinical utility must be established through evidence showing that test results directly influence management decisions, support diagnostic clarity, or guide therapy. The evidence supports restricting laboratory services to situations where testing provides actionable information.

American Society for Clinical Laboratory Science (ASCLS)

ASCLS has published evidence-based recommendations showing that duplicative testing and excessively frequent retesting contribute to unnecessary healthcare utilization without improving patient outcomes.[8-10] Studies summarized in ASCLS position papers note that repeating laboratory tests within short intervals rarely provides new clinically meaningful information unless clinical circumstances have changed. Repeat testing often reflects habit, standing orders, or convenience rather than a change in diagnosis or treatment needs. ASCLS also highlights that unnecessary repeated testing increases the likelihood of incidental findings, which may trigger further unnecessary procedures. Health-system interventions informed by ASCLS recommendations (e.g. implementing minimum retesting intervals) have been shown to significantly reduce redundant testing while maintaining high-quality patient care. This evidence supports limiting repeat testing unless there is a documented clinical indication.

International Federation of Clinical Chemistry (IFCC)

IFCC guidance distinguishes between standard and non-standard laboratory tests based on validation, methodology, and clinical relevance.[11,12] Evidence compiled by IFCC demonstrates that standard tests performed in accredited, quality-controlled laboratories consistently provide reliable and clinically interpretable results. Conversely, IFCC reviews show that non-standard tests—such as those relying on novel biomarkers, proprietary algorithms, or unconventional specimen types—frequently lack the necessary analytical and clinical validation to support clinical use. Studies referenced in IFCC consensus statements reveal that unvalidated testing methods produce inconsistent results across laboratories and may not correlate with clinical outcomes or established diagnostic criteria. IFCC therefore advises cautious adoption of such tests until adequate validation is available. This evidence base supports restricting coverage to standard, validated laboratory services and excluding tests that lack demonstrated analytical validity or clinical utility.

U.S. Preventive Services Task Force (USPSTF)

The U.S. Preventive Services Task Force (USPSTF) provides the national evidentiary framework for determining when preventive screening tests, including laboratory tests, demonstrably improve health outcomes in asymptomatic individuals.[13-17] USPSTF assigns each preventive service a letter grade based on a rigorous, systematic review of benefits and harms. Tests receiving A or B grades are supported by high or moderate certainty of a substantial or moderate net benefit and are recommended for routine preventive use; this includes laboratory-based screenings such as lipid disorders, diabetes, hepatitis C, HIV, and syphilis among specific populations.

Conversely, tests receiving D grades are recommended against due to evidence of little to no net benefit or potential harm, while I statements reflect insufficient evidence to assess net benefit. This framework highlights that many commonly ordered laboratory tests lack evidence to justify routine population screening and may expose patients to unnecessary follow-up testing or clinical cascades. Incorporating USPSTF A/B recommendations, and avoiding D/I-rated screening, supports evidence-based, high-value utilization of laboratory services and aligns with national preventive care standards.

EVIDENCE SUMMARY

Laboratory testing must be grounded in evidence demonstrating that a test is analytically valid, clinically useful, and likely to influence diagnosis or management. Research across large multisite quality-improvement programs shows that unnecessary or duplicative testing can trigger false positives and downstream cascades, including follow-up imaging, consultations, and invasive procedures, without improving outcomes. Evidence also demonstrates that tests lacking validated accuracy, precision, and reproducibility increase the risk of error, leading to missed or incorrect diagnoses. Even when analytically sound, testing offers little value if results do not change clinical decisions, and overuse in low-risk or asymptomatic populations can create avoidable harms. Studies examining retesting practices further show that repeating tests too frequently rarely provides new clinical information and may drive incidental findings and additional procedures. High-quality laboratory practice therefore requires that testing be clinically justified, actionable, performed using validated methods, and aligned with evidence-supported preventive screening recommendations to ensure meaningful benefit and avoid low-value care.

HEALTH EQUITY CONSIDERATIONS

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.

The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online here.

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Novis DA. Detecting and preventing the occurrence of errors in the practices of laboratory medicine and anatomic pathology: 15 years' experience with the College of American Pathologists' Q-PROBES and Q-TRACKS programs. *Clinics in laboratory medicine.* 2004;24(4):965-978
2. Darcy TP, Barasch SP, Souers RJ, Perrotta PL. Test cancellation: a college of American Pathologists Q-probes study. *Archives of pathology & laboratory medicine.* 2016;140(2):125-129
3. College of American Pathologists. Quality Management Tools. https://www.cap.org/laboratory-improvement/quality-management-programs. Published 2026. Accessed 2/23/2026.
4. Clinical & Laboratory Standards Institute (CLSI). CLSI Standards Database and Method Evaluation Catalog https://clsi.org/. Published 2026. Accessed 2/23/2026.
5. Lynch KL. CLSI C62-A: a new standard for clinical mass spectrometry. *Clinical chemistry.* 2016;62(1):24-29
6. Nichols JH, Alter D, Chen Y, et al. AACC guidance document on management of point-of-care testing. *The Journal of Applied Laboratory Medicine.* 2020;5(4):762-787
7. Cornish NE, Morgan DJ, Saitman A, Sidiropoulos N, Zahner CJ, Christenson RH. Diagnostic Stewardship in Action: Advancing Healthcare Value. In. Vol 10: Oxford University Press US; 2025:1-3.
8. American Society for Clinical Laboratory Science (ASCLS). Scope of Practice and Personnel Standards. https://ascls.org/scope-of-practice/. Published 2024. Accessed 2/23/2026.
9. Royal College of Pathologists. National minimum retesting intervals in pathology. https://www.rcpath.org/static/253e8950-3721-4aa2-8ddd4bd94f73040e/g147_national-minimum_retesting_intervals_in_pathology.pdf. Published 2021. Accessed 2/23/2026.

10. CADTH Advisory Panel. CADTH Health Technology Review Recommendation- Advisory Panel Guidance on Minimum Retesting Intervals for Lab Tests. https://www.cda-amc.ca/sites/default/files/hta-he/HC0078_Guidance_Report_final.pdf. Published 2024. Accessed 2/23/2026.
11. International Federation of Clinical Chemistry and Laboratory Medicine. IFCC Laboratory Medicine Practice Guidelines. https://apfcb.org/assets/pdf/IFCC%20Laboratory%20Medicine%20Practice%20Guidelines_2023.pdf. Published 2024. Accessed
12. Wheeler SE, Blasutig IM, Dabla PK, et al. Quality standards and internal quality control practices in medical laboratories: an IFCC global survey of member societies. *Clinical Chemistry and Laboratory Medicine (CCLM).* 2023;61(12):2094-2101
13. US Preventive Services Task Force. A & B Recommendations. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations. Published 2026. Accessed 2/23/2026.
14. US Preventive Services Task Force. Screening for colorectal cancer: US Preventive Services Task Force recommendation statement. *Jama.* 2016;315(23):2564-2575
15. US Preventive Services Task Force. Screening for prediabetes and type 2 diabetes: US Preventive Services Task Force recommendation statement. *Jama.* 2021;326(8):736-743
16. US Preventive Services Task Force. Screening for hepatitis B virus infection in adolescents and adults: US Preventive Services Task Force recommendation statement. *Jama.* 2020;324(23):2415-2422
17. US Preventive Services Task Force. Screening for Rh (D) incompatibility: recommendation statement. *American Family Physician.* 2005;72(6):1087-1088

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
6/2026	New policy.