PreferredOne®

Department of Origin: Integrated Healthcare Services	**Effective Date:** 10/14/24
Approved by: Chief Medical Officer	**Date Approved:** 10/10/24
Clinical Policy Document: Laboratory Tests	**Replaces Effective Clinical Policy Dated:** 10/18/23
Reference #: MP/L001	**Page:** 1 of 3

PURPOSE:
The intent of this clinical policy is to provide coverage guidelines for laboratory testing.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

COVERAGE:

I. The test is ordered and submitted from or under the direction of a provider working within their scope of practice; and

II. Each test has been approved for its intended use by the appropriate regulatory/oversight body (implies analytic validity); and

III. Each test has sufficient sensitivity or specificity (*clinical validity*) for targeting the member's specific clinical condition; and

IV. The result of each test has appropriate evidence that it will directly impact clinical decision-making and clinical care (clinical utility); and

V. Laboratory tests are covered when the individual test or panel meets the Plan's definition of a *standard laboratory test*, as reflected in this policy.

EXCLUSIONS (not limited to):
Refer to member's Certificate of Coverage or Summary Plan Description

DEFINITIONS:
Analytic Validity:
How accurately and reliably the test measures the genotype of interest. A major component in the validation of an analytical technique is the technique's ability to accurately determine the presence of the substance it is seeking. It must measure the target substance without a great range of variation over a number of trials. The technique also must be proven to work reliably at multiple labs to be validated by this testing.

Clinical Laboratory Improvement Amendments (CLIA):
United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research.

Clinical Utility:
How likely the test is to significantly improve patient outcomes. The evidence of improved measurable clinical outcomes, and its usefulness and added value to patient management decision-making compared with current management without the testing.

Clinical Validity:
How consistently and accurately the test detects or predicts the intermediate or final outcomes of interest.

Companion Diagnostic:
A companion diagnostic is a medical device, often an in vitro device, which provides information that is essential for the safe and effective use of a corresponding drug or biological product. The test helps a health care professional determine whether a particular therapeutic product's benefits to patients will outweigh any potential serious side effects or risks.

In Vitro Diagnostics (IVD):
Those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. IVDs are regulated by the US Food and Drug Administration (FDA) under the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act). IVDs are medical devices subject to premarket and postmarket approval, depending on their risk profiles. Use of IVDs in a laboratory setting to deliver clinical results is regulated by the Centers for Medicare and Medicaid Services (CMS) under the 1988 Clinical Laboratory Improvement Amendments (CLIA). Devices are classified into 3 separate risk categories: class I (low risk), II (moderate risk), class III (high risk), which determines their pathway to FDA marketing authorization. FDA regulation of IVDs focuses on safety and effectiveness of the device, primarily as demonstrated through clinical and analytic performance, whereas CMS regulation through CLIA focuses on laboratory quality.

Laboratory Developed Test (LDT):
Some IVDs are known as LDTs. LDTs, also known as home brew or in-house tests, are developed in and by laboratories in a variety of settings (e.g., hospital-based laboratories, independent laboratories) and are then offered only by those laboratories, compared with traditional laboratory tests, which represent most of the market and are typically marketed commercially as kits and distributed to several laboratories. These kits often include all of the necessary components to perform testing in a CLIA-certified laboratory. These traditional laboratory tests, which are broadly available commercially, are subject to FDA regulation per the FD&C Act. Depending on the risk profile of the test, a premarket review process may apply. Certain low-risk tests are exempt from premarket review; moderate-risk tests generally are require test manufacturers to provide evidence that their test are "substantially equivalent" to existing tests under the 510(k) program, and high-risk tests generally are reviewed for safety and effectiveness under the more rigorous premarket approval (PMA) process, reserved for class III IVDs.

Non-Standard Laboratory Test:
Not meeting the criteria of a standard laboratory test defined below or possessing one of the following attributes:

- A test proposed for the diagnosis and/or monitoring of a condition or disease state which is inconsistent with medical standards and accepted practice parameters of the community.
- A test using a methodology other than that employed in standard medical practice (eg, spectroscopy analysis instead of a standard culture for microorganisms).
- A test using a specimen type other than that employed in standard medical practice (eg, saliva specimen instead of a standard blood collection).

- Panels comprised of numerous analytes – a high number of which do not impart clinical utility to the diagnosis or management of the disease or condition under consideration (eg, a hormone panel measuring multiple analytes when two analytes are recognized as standard medical practice).
- Test results reported in laboratory reporting values not recognized as national or international values employed in standard laboratory practice (eg, low-medium-high versus micrograms/liter).
- Test is performed at a frequency or volume that is not consistent with medical standards and accepted practice parameters of the community.

Standard Laboratory Test or Panel:
A test/panel performed in a *CLIA*-certified clinical laboratory setting; and recognized as clinically valid by at least one of the following professional organizations (Note: list may not be exhaustive)

- American Society of Clinical Pathology (ASCP)
- Association for Molecular Pathology (AMP)
- Clinical and Laboratory Standards Institute (CLSI)
- College of American Pathologists (CAP)
- National Committee for Clinical Laboratory Standard (NCCLS)

REFERENCES:

1. Clinical Policy: Coverage Determination Guidelines MP/C009
2. Clinical Policy: Levels of Evidence (LOE) and the Evaluation of Health Care Services MP/L004
3. In Vitro Companion Diagnostic Devices. Guidance for Industry and Food and Drug Administration Staff. Document issued on: August 6, 2014. Content current as of: 09/27/18. Retrieved from http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm262327.pdf. Accessed 10-09-24.

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PCHP:
Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

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If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
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Fax: 763.847.4010
customerservice@preferredone.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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