LifeWise
Health Plan of Washington

MEDICAL POLICY – 2.04.520

Laboratory Testing Investigational Services

BCBSA Ref. Policy: 2.04.159

Effective Date:	Apr. 4, 2024
Last Revised:	July 1, 2024
Replaces:	N/A

RELATED MEDICAL POLICIES:

2.04.26	Fecal Analysis in the Diagnosis of Intestinal Dysbiosis
2.04.73	Intracellular Micronutrient Analysis
2.04.119	Multibiomarker Disease Activity Blood Test for Rheumatoid Arthritis
2.04.123	Serum Biomarker Panel Testing for Systemic Lupus Erythematosus and Other Connective Tissue Diseases
2.04.152	Maternal Serum Biomarkers for Prediction of Adverse Obstetric Outcomes
2.04.509	Cardiovascular Risk Panels
2.04.514	Protein Biomarkers for the Diagnosis and Cancer Risk Assessment of Prostate Cancer

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POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

There are many tests available to check for diseases or future health risks using genes and molecules. This policy focuses on tests that diagnose diseases that were not discussed in other policies. If there is another review about the same test, its conclusions are more important than the ones here. The main reason for including a test in this review is because there isn't much evidence showing how useful it is for doctors and patients. This policy gives information about several laboratory tests that have not been proven to be helpful in treating people's health, there isn't enough evidence to say they make a positive difference.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Test	Investigational
Tests identified in this policy	**All tests listed in this policy are considered investigational as there is insufficient evidence to determine that the technology results in an improvement in the net health outcome**

Coding

Code	Description
CPT	
0112U	Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug-resistance gene (MicroGenDx)
0365U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of bladder cancer (Oncuria Detect)
0366U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of recurrent bladder cancer (Oncuria Monitor)
0367U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm reported as a risk score for probability of rapid recurrence of recurrent or persistent cancer following transurethral resection (Oncuria Predict)
0371U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogen, semiquantitative identification, DNA from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative polymerase chain reaction (qPCR), urine (Qlear UTI) (new code effective 1/1/2024)
0372U	Infectious disease (genitourinary pathogens), antibiotic-resistance gene detection, multiplex amplified probe technique, urine, reported as an antimicrobial stewardship risk score (Qclear UTI-Reflex ABR) (new code effective 1/1/2024)
0373U	Infectious agent detection by nucleic acid (DNA and RNA), respiratory tract infection, 17 bacteria, 8 fungus, 13 virus, and 16 antibiotic-resistance genes, multiplex amplified probe technique, upper or lower respiratory specimen (Respiratory Pathogen with ABR [RPX]) (new code effective 1/1/2024)
0374U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 21 bacterial and fungal organisms and identification of 21 associated

Code	Description
	antibiotic-resistance genes, multiplex amplified probe technique, urine (Urogenital Pathogen with Rx Panel [UPX]) (new code effective 1/1/2024)
0377U	Cardiovascular disease, quantification of advanced serum or plasma lipoprotein profile, by nuclear magnetic resonance (NMR) spectrometry with report of a lipoprotein profile (including 23 variables) (Liposcale) (new code effective 1/1/2024)
0384U	Nephrology (chronic kidney disease), carboxymethyllysine, methylglyoxal hydroimidazolone, and carboxyethyl lysine by liquid chromatography with tandem mass spectrometry (LC-MS/MS) and HbA1c and estimated glomerular filtration rate (GFR), with risk score reported for predictive progression to high-stage kidney disease (NaviDKD Predictive Diagnostic Screening for Kidney Health) (new code effective 1/1/2024)
0385U	Nephrology (chronic kidney disease), apolipoprotein A4 (ApoA4), CD5 antigen-like (CD5L), and insulin-like growth factor binding protein 3 (IGFBP3) by enzyme-linked immunoassay (ELISA), plasma, algorithm combining results with HDL, estimated glomerular filtration rate (GFR) and clinical data reported as a risk score for developing diabetic kidney disease (PromarkerD) (new code effective 1/1/2024)
0390U	Obstetrics (preeclampsia), kinase insert domain receptor (KDR), Endoglin (ENG), and retinol-binding protein 4 (RBP4), by immunoassay, serum, algorithum reported as risk score (i.e., PEPredictDx by OncoOmicsDx Laboratory mProbe)
0390U	Obstetrics (preeclampsia), kinase insert domain receptor (KDR), Endoglin (ENG), and retinol-binding protein 4 (RBP4), by immunoassay, serum, algorithm reported as a risk score (PEPredictDx by OncoOmicsDx Laboratory mProbe)
0406U	Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4-carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer (new code effective 10/1/2023)
0415U	Cardiovascular disease (acute coronary syndrome [ACS]), IL-16, FAS, FASLigand, HGF, CTACK, EOTAXIN, and MCP-3 by immunoassay combined with age, sex, family history, and personal history of diabetes, blood, algorithm reported as a 5-year (deleted risk) score for ACS (new code effective 10/1/2023)
0418U	Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score (new code effective 10/1/2023)
0421U	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 8 RNA markers (GAPDH, SMAD4, ACY1, AREG, CDH1, KRAS, TNFRSF10B, EGLN2) and fecal hemoglobin, algorithm reported as a positive or negative for colorectal cancer risk (new code effective 1/1/2024)
0450U	Oncology (multiple myeloma), liquid chromatography with tandem mass spectrometry (LC-MS/MS), monoclonal paraprotein sequencing analysis, serum, results reported as baseline presence or absence of detectable clonotypic peptides (new code effective 7/1/2024)

Code	Description
0451U	Oncology (multiple myeloma), LC-MS/MS, peptide ion quantification, serum, results compared with baseline to determine monoclonal paraprotein abundance (new code effective 7/1/2024)
0457U	Perfluoroalkyl substances (PFAS) (e.g., perfluorooctanoic acid, perfluorooctane sulfonic acid), 9 PFAS compounds by LC-MS/MS, plasma or serum, quantitative (new code effective 7/1/2024)
0458U	Oncology (breast cancer), S100A8 and S100A9, by enzyme-linked immunosorbent assay (ELISA), tear fluid with age, algorithm reported as a risk score (new code effective 7/1/2024)
0462U	Melatonin levels test, sleep study, 7 or 9 sample melatonin profile (cortisol optional), enzyme-linked immunosorbent assay (ELISA), saliva, screening/preliminary (new code effective 7/1/2024)
0463U	Oncology (cervix), mRNA gene expression profiling of 14 biomarkers (E6 and E7 of the highest-risk human papillomavirus [HPV] types 16, 18, 31, 33, 45, 52, 58), by real-time nucleic acid sequence-based amplification (NASBA), exo- or endocervical epithelial cells, algorithm reported as positive or negative for increased risk of cervical dysplasia or cancer for each biomarker (new code effective 7/1/2024)
0468U	Hepatology (nonalcoholic steatohepatitis [NASH]), miR-34a-5p, alpha 2-macroglobulin, YKL40, HbA1c, serum and whole blood, algorithm reported as a single score for NASH activity and fibrosis (new code effective 7/1/2024)
0470U	Oncology (oropharyngeal), detection of minimal residual disease by next-generation sequencing (NGS) based quantitative evaluation of 8 DNA targets, cell-free HPV 16 and 18 DNA from plasma (new code effective 7/1/2024)
0472U	Carbonic anhydrase VI (CA VI), parotid specific/secretory protein (PSP) and salivary protein (SP1) IgG, IgM, and IgA antibodies, enzyme-linked immunosorbent assay (ELISA), semiqualitative, blood, reported as predictive evidence of early Sjogren syndrome (new code effective 7/1/2024)
84999	Unlisted chemistry procedure (when used for known error test, Prometheus precision-guided dosing PredictrPK test).

Related Information

N/A

Evidence Review

Description

There are numerous commercially available genetic and molecular diagnostic, prognostic, and therapeutic tests for individuals with certain diseases or asymptomatic individuals with future risk. This policy relates to diagnostic tests not addressed in a separate policy. If a separate policy exists, then conclusions reached there supersede conclusions here. The main criterion for inclusion in this policy is the limited evidence on the clinical utility for the test. As these tests do not have clinical utility, the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Background

This policy applies if there is not a separate policy that outlines specific criteria for testing. If a separate policy does exist, then the criteria for medical necessity therein supersede the guidelines herein.

This policy addresses laboratory services considered to be investigational. These tests are often available on a clinical basis before the required and necessary evidence base to support clinical validity and utility is established. Because these tests are often proprietary, there may be no independent test evaluation data available in the early stages to support the laboratory's claims regarding test performance and utility. While studies using these tests may generate information that may help elucidate the biologic mechanisms of disease and eventually help design treatments, the tests listed in this policy are currently in a developmental phase, with limited evidence of clinical utility for diagnosis, prognosis, or risk assessment.

Summary of Evidence

For individuals with various indications for diagnostic, prognostic, therapeutic, or future risk assessment testing who receive the tests addressed in this policy, the evidence on clinical utility is insufficient or non-evaluable. For each test addressed, a brief description is provided for informational purposes. No formal evidence review was conducted. To sufficiently evaluate clinical utility, features of well-defined test, intended use, and clinical management pathway characteristics are summarized. If it is determined that enough evidence has accumulated to

reevaluate its potential clinical utility, the test will be removed from this review and addressed separately. The lack of demonstrated clinical utility of these tests is based on the following factors: (1) there is no or extremely limited published data addressing the test; and/or (2) it is unclear where in the clinical pathway the test fits (replacement, triage, add-on); and/or (3) it is unclear how the test leads to changes in management that would improve health outcomes and/or avoiding existing burdensome and invasive testing; and/or (4) thresholds for decision making have not been established; (5) and/or the outcome from the test result does not result in a clinically meaningful improvement relative to the outcomes(s) obtained without the test.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05276466[a]	Assessment of Urinary Polymerase Chain Reaction (PCR) and Next Generation Sequencing (NGS) Technology in the Evaluation and Management of Females With Chronic Bladder Pain and Cystitis-like Symptoms	100	Dec 2023
NCT05287438[a]	Next Generation Sequencing Versus Traditional Cultures for Clinically Infected Penile Implants: Impact of Culture Identification on Outcomes	40	Oct 2024

NCT: National Clinical Trial.

[a] Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Gastroenterology

In 2023, the American College of Gastroenterology published a clinical practice update for the diagnosis and management of celiac disease.[27], A recommendation for genetic testing using a multigene panel test (e.g., Celiac PLUS) was not included.

In 2018, the American College of Gastroenterology practice guidelines on Crohn disease state that genetic and routine serologic testing is not indicated to establish the diagnosis of Crohn's disease.[28]

American Urological Association et al

In 2019, the American Urological Association (AUA) published joint guidelines with the Canadian Urological Association (CUA) and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) on the management of recurrent uncomplicated urinary tract infections in women.[29] Regarding the use of polymerase chain reaction (PCR) and next-generation sequencing (NGS) techniques for the identification of bacterial species, the guideline states that "more evidence is needed before these technologies become incorporated into the guideline, as there is concern that adoption of this technology in the evaluation of lower urinary tract symptoms may lead to over treatment with antibiotics."

In 2016, the AUA published joint guidelines with the Society of Urologic Oncology on the diagnosis and treatment of non-muscle invasive bladder cancer.[30] For use of urinary biomarkers after diagnosis, the guidelines state: "a clinician should not use urinary biomarkers in place of cystoscopic evaluation" (Strong Recommendation; Evidence Strength: Grade B); that "in a patient with a history of low-risk cancer and a normal cystoscopy, a clinician should not routinely use a urinary biomarker or cytology during surveillance (Expert Opinion); and that "in a patient with non-muscle invasive bladder cancer (NMIBC), a clinician may use biomarkers to assess response to intravesical Bacillus Calmette-Guerin (BCG) (UroVysion FISH) and adjudicate equivocal cytology (UroVysion FISH and ImmunoCyt) (Expert Opinion)."

National Comprehensive Cancer Network

NCCN clinical practice guidelines on bladder cancer v.3.2023 state the following regarding urine molecular tests for urothelial tumor markers [31] Many of these tests have a better sensitivity for detecting bladder cancer than urinary cytology, but specificity is lower. Considering this, evaluation of urinary urothelial tumor markers may be considered during surveillance of high-risk non-muscle invasive bladder cancer (NMIBC). However, it remains unclear whether these tests offer additional useful information for detection and management of NMIBC. Therefore, the panel considers this to be a category 2B recommendation.

NCCN clinical practice guidelines on colon cancer (v.3.2023) state that "it has not been established if molecular markers (other than MSI-H/dMMR) are useful in treatment determination (predictive markers) and prognosis.[32]

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA). Laboratories that offer laboratory-developed tests must be licensed by the CLIA for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of these tests.

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History

Date	Comments
09/01/23	New policy, approved August 8, 2023. Policy created with literature review through May 12, 2023. All tests listed in this policy are considered investigational. Added CPT codes 0112U, and 0365U-0367U.
10/01/23	Coding update. Added new CPT codes 0406U, 0415U and 0418U.
01/01/24	Interim Review, approved December 11, 2023. Policy updated with literature review through September 25, 2023. Added CPT codes 0371U, 0372U, 0373U, 0374U, 0377U, 0384U, 0385U, and 84999. Added CPT code 81382, effective April 4, 2024, following a 90-day notification. Added CPT code 0390U.
04/01/24	Coding update. Added CPT codes 0390U and 81382.
05/01/24	Minor update to related policies. 2.04.100 was replaced with 2.04.509 Cardiovascular Risk Panels.
07/01/24	Coding update. Removed CPT code 81382. Added new CPT codes 0450U, 0451U, 0457U, 0458U, 0462U, 0463U, 0468U, 0470U and 0472U.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and

local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA).

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

LifeWise

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Language Assistance

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ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-817-3056 (መስማት ለተሳናቸው: 711).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-817-3056 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-817-3056 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-817-3056 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-817-3056 (TTY: 711).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 800-817-3056 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-817-3056 (TTY: 711).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-817-3056 (ATS : 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-817-3056 (TTY: 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-817-3056 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-817-3056 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-817-3056 (TTY: 711) تماس بگیرید.