Medical Coverage Policy | Proprietary Laboratory Analyses (PLA) and Multianalyte Assays with Algorithmic Analyses (MAAA)

EFFECTIVE DATE: 11|01|2024
POLICY LAST REVIEWED: 07|17|2024

OVERVIEW

Proprietary Laboratory Analyses (PLA) codes are alpha-numeric CPT codes with a corresponding descriptor for labs or manufacturers that want to more specifically identify their test.

This policy indicates genetic testing services:

- for which prior authorization is required for Medicare Advantage Plans or recommended for Commercial Products via the online authorization tool, or
- that are not medically necessary, or
- not covered, or
- covered

For information regarding genetic testing CPT codes that are not Proprietary Laboratory Analyses Codes (PLA) codes or Multianalyte Assays with Algorithmic Analyses (MAAA) codes, please see the Genetic Testing Services Policy.

MEDICAL CRITERIA

Generally, InterQual criteria is used to determine medical necessity for a majority of genetic testing, and is found in the online authorization tool:

https://www.bcbsri.com/BCBSRIWeb/Login.do?redirectTo=/providers/preauth/preauthProviderOverview.jsp

NOTE REGARDING PANEL TESTING: Panel tests are subject to additional criteria. Please refer to the Policy Statement and Prior Authorization sections below for specific information regarding panel testing before utilizing the medical necessity criteria set forth below.

The following general criteria is used in the online authorization tool depending on the category of screening, when separate criteria is not identified for the specific test being requested.

Carrier screening (preconception or prenatal testing) for genetic diseases is considered medically when the following criteria are met:

- One or both individuals have a first- or second-degree relative (see definitions below) who is affected;
- One individual is known to be a carrier;
- One or both individuals are members of a population known to have a carrier rate that exceeds a threshold considered appropriate for testing for a particular condition; AND
- Previous carrier screening or individual targeted gene testing for the gene variant(s) of interest has not been performed.

First-degree relatives include a biological parent, brother, sister, or child.
Second-degree relatives include a biologic grandparent, aunt, uncle, niece, nephew, grandchildren, and half-sibling.

Genetic screening or testing for genetic or hereditary conditions is considered medically necessary when the diagnostic test of the individual's germline will benefit the individual and one of the following criteria is met:

- To confirm a suspected diagnosis in a patient with signs and/or symptoms of the condition
- To identify a causative etiology for a clinical syndrome, for which there are multiple possible underlying conditions
- Testing an asymptomatic individual to determine future risk of disease

Genetic testing for cancer is considered medically necessary when one of the following criteria is met:

- Testing an asymptomatic patient to determine future risk of cancer
- Therapeutic testing of cancer cells from an affected individual to benefit the individual by directing targeted treatment based on specific somatic variants.

PRIOR AUTHORIZATION

For those tests in which prior authorization is indicated in the attached code grid, prior authorization is required for Medicare Advantage Plans and recommended for Commercial Products.

Requests for authorization of genetic testing should be submitted via the BCBSRI online prior authorization tool, which is available to BCBSRI-participating providers. All other providers may fax a prior authorization request to Utilization Management at (401) 272-8885.

If a genetic test is not found in the online authorization tool, please fax the request to Utilization Management at (401) 272-8885.

Panel testing: prior authorization is required for each component and/or gene/gene variant of panel testing when the panel is represented by multiple CPT codes. Each individual CPT code must be entered into and processed through the online authorization tool independently.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

For services in which prior authorization is indicated, genetic testing may be considered medically necessary when the criteria in the online authorization tool and/or BCBSRI's Policies has been met. Please see Related Policies below for additional policies indicating criteria and coverage requirements for certain genetic testing.

Genetic testing services are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products when:

- there is insufficient clinical evidence or strength of recommendation,
- results would not reasonably be used in management of a patient,
- services are unlikely to impact therapeutic decision-making in the clinical management of the patient.

There is not enough research to show that genetic panels can lead to better health outcomes for patients. When there is not enough research to show that a gene and/or gene variant alone in a genetic panel test may be used to manage treatment decisions and improve net health outcomes, then the entire genetic panel test is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products.

For coverage of any panel test filed with a specific individual CPT code, please refer to the code grid in this policy and/or the Genetic Testing Services policy.

For some genetic tests, medical necessity, and coverage of the test, is determined by the diagnosis code submitted with the claim. Please refer to the codes on the attached grid and the information in the Comments column for diagnosis coding or for a Related Policy if applicable.

Laboratories are not allowed to obtain clinical authorization or participate in the authorization process on behalf of the ordering physician. Only the ordering physician shall be involved in the authorization, appeal or other administrative processes related to prior authorization/medical necessity.

In no circumstance shall a laboratory or a physician/provider use a representative of a laboratory or anyone with a relationship to a laboratory and/or a third party to obtain authorization on behalf of the ordering physician, to facilitate any portion of the authorization process or any subsequent appeal of a claim where the authorization process was not followed and/or a denial for clinical appropriateness was issued, including any element of the preparation of necessary documentation of clinical appropriateness. If a laboratory or a third party is found to be supporting any portion of the authorization process, BCBSRI will deem the action a violation of this policy and severe action will be taken up to and including termination from the BCBSRI provider network. If a laboratory provides a laboratory service that has not been authorized, the service will be denied as the financial liability of the participating laboratory and may not be billed to the member."

Commercial Products
Some genetic testing services are not covered and a contract exclusion for any self-funded group that has excluded the expanded coverage of biomarker testing related to the state mandate, R.I.G.L**. §27-19-81** described in the Biomarker Testing Mandate policy. For these groups, a list of which genetic testing services are covered with prior authorization, are not medically necessary or are not covered because they are a contract exclusion can be found in the Coding section of the Genetic Testing Services or Proprietary Laboratory Analyses policies. Please refer to the appropriate Benefit Booklet to determine whether the member's plan has customized benefit coverage. Please refer to the list of Related Policies for more information.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable laboratory testing and not covered/not medically necessary benefits/coverage.

BACKGROUND

In response to the Protecting Access to Medicare Act of 2014 (PAMA), which focuses on payment and coding of clinical laboratory studies paid for under the Medicare Clinical Laboratory Fee Schedule (CLFS), the AMA has developed a category of CPT codes, known as Proprietary Laboratory Analyses (PLA), which are released on a quarterly basis.

PLA codes describe proprietary clinical laboratory analyses and can be provided either by a single ("sole-source") laboratory or licensed or marketed to multiple providing laboratories (eg, cleared or approved by the Food and Drug Administration [FDA]). These codes include advanced diagnostic laboratory tests (ADLTs) and clinical diagnostic laboratory tests (CDLTs) as defined under the Protecting Access to Medicare Act (PAMA) of 2014.

PLA codes do not require adherence to CPT Category I Code Criteria or American Medical Association (AMA) review for clinical utility. Additionally, they may or may not be FDA approved. The standards for inclusion in this section are:

- The test must be commercially available in the United States for use on human specimens, and
- The clinical laboratory or manufacturer that offers the test must request the code.

When a PLA code is available to report a given proprietary laboratory service, that PLA code takes precedence. The service should not be reported with any other CPT code(s) and other CPT code(s) should not be used to report services that may be reported with that specific PLA code. PLA codes are contained in a Category I subsection of the Pathology/Laboratory CPT codes.

MultiAnalyte Assays with Algorithmic Analyses
Multianalyte Assays with Algorithmic Analyses (MAAAs) are procedures that utilize multiple results derived from panels of analyses of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid-based assays (eg, proteins, polypeptides, lipids, carbohydrates). Algorithmic analysis using the results of these assays as well as other patient information (if used) is then performed and reported typically as a numeric score(s) or as a probability. MAAAs are typically unique to a single clinical

laboratory or manufacturer. MAAAs, by nature, are typically unique to a single clinical laboratory or manufacturer.

Genetic test panels are available for many clinical conditions. Genetic test panels may be focused to a few genes or include a large number of genes. The advantage of genetic test panels is the ability to analyze many genes simultaneously, potentially improving the breadth and efficiency of the genetic workup. A disadvantage of genetic test panels is that the results may provide information on genetic variants that are of unclear clinical significance or which would not lead to changes in patient management. These results may potentially cause harm by leading to additional unnecessary interventions and anxiety that would not otherwise be considered based on the patient's clinical presentation and/or family history.

For individuals who have a personal and/or family history suggesting an inherited cancer syndrome who receive expanded gene panel testing, the evidence includes reports describing the diagnostic yield of expanded gene panels. Relevant outcomes are overall survival, disease-specific survival, and test validity. Studies of gene panel testing for genetic cancer risk assessment have reported primarily on the frequency with which variants are identified. The rates of variants of uncertain significance for gene panels are significant and increase in proportion with panel size, reaching nearly 50% for large gene panels. Variants included in these panels are associated with varying levels of risk of developing cancer. Published data on clinical utility are lacking, and it is unknown whether the use of these panels improves health outcomes. Only some variants included on panels are associated with a high risk of developing a well-defined cancer syndrome for which there are established clinical management guidelines. Many expanded panels include genetic variants considered to be of moderate or low penetrance, and clinical management recommendations for these genes are not well-defined. The lack of clinical management pathways for variants of uncertain clinical significance increases the potential for harm. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

See the attached grid for Medicare Advantage Plans and Commercial Products coverage of PLA codes and indication of which codes may be covered, medically necessary if criteria are met, not medically necessary or not covered.

PLA and MAAA Codes and Coverage Effective 11/1/2024

RELATED POLICIES

Assays of Genetic Expression in Tumor Tissue as a Technique to Determine Prognosis in Patients with Breast Cancer
Biomarker Testing Mandate
Blood Product Molecular Antigen Typing
Circulating Tumor DNA and Circulating Tumor Cells for Cancer Management (Liquid Biopsy)
Comprehensive Genomic Profiling for Selecting Targeted Cancer Therapies
Evaluation of Biomarkers for Alzheimer's Disease
Gene Expression Profiling and Protein Biomarkers for Prostate Cancer Management
Gene Expression Profiling for Cutaneous Melanoma
Genetic and Protein Biomarkers for the Diagnosis and Cancer Risk Assessment of Prostate Cancer
Genetic Testing for Diagnosis and Management of Mental Health Conditions
Genetic Testing for Duchenne and Becker Muscular Dystrophy
Genetic Testing for Epilepsy
Genetic Testing for Mitochondrial Disorders
Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasm
Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment and Immunotherapy in Breast Cancer
Identification of Microorganisms Using Nucleic Acid Probes
Invasive Prenatal (Fetal) Diagnostic Testing
Laboratory Testing Investigational Services

Laboratory Tests Post Transplant and for Heart Failure
Lung Liquid Biopsy
Lyme Disease Diagnosis and Treatment Mandate
Mass Spectrometry (MS) Testing in Monoclonal Gammopathy
Medicare Advantage Plans National and Local Coverage Determinations
Minimal Residual Disease Testing for Cancer
Molecular Markers in Fine Needle Aspirates of the Thyroid
Molecular Testing in the Management of Pulmonary Nodules
Multimarker Serum Testing Related to Ovarian Cancer
Multitarget Polymerase Chain Reaction Testing for Diagnosis of Bacterial Vaginosis
Next Generation Sequencing for Solid Tumors
Noninvasive Techniques for the Evaluation and Monitoring of Patients with Chronic Liver Disease
Preimplantation Genetic Testing
Prognostic and Predictive Molecular Classifiers for Bladder Cancer
Prostate Cancer Detection with IsoPSA
Serologic Genetic and Molecular Screening for Colorectal Cancer
Urinary Biomarkers for Cancer Screening, Diagnosis and Surveillance
Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders

PUBLISHED

Provider Update, May 2024
Provider Update, November 2023
Provider Update, May 2023
Provider Update, March 2022
Provider Update, August 2021

REFERENCES

American Medical Association, CPT 2023 Professional Edition

Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD): Molecular Pathology Procedures (L35000)

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS