Medical Coverage Policy | Proprietary Laboratory Analyses (PLA)

EFFECTIVE DATE: 10|01|2019
POLICY LAST UPDATED: 05|31|2023

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.

MEDICAL CRITERIA
Medicare Advantage Plans and Commercial Products
For services that require prior authorization, please refer to the Related Policies identified in the Code and Coverage Grid found in the Coding Section of this policy for where to find appropriate medical criteria.

PRIOR AUTHORIZATION
Medicare Advantage Plans and Commercial Products
For services that require prior authorization, please refer to the Related Policies identified in the Code and Coverage Grid found in the Coding Section of this policy for where to find appropriate medical criteria.

POLICY STATEMENT
Medicare Advantage Plans and Commercial Products
Coverage determinations vary by code. Please refer to the grid in the Coding Section for the coverage determination for the service being rendered.

For Commercial Products, in absence of a specific policy, some Proprietary Laboratory Analyses codes are considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes. See Coding Section for details.

Medicare Advantage Plans and Commercial Products
Genetic testing is considered medically necessary when the criteria in the online authorization tool and/or BCBSRI's Policy has been met.

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."

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.

CODING

See the attached grid for BlueCHiP for Medicare and Commercial Products coverage of PLA codes.

Proprietary Laboratory Analyses (PLA) Codes and Coverage

RELATED POLICIES

Medicare Advantage Plans National and Local Coverage Determinations
Comprehensive Genomic Profiling for Selecting Targeted Cancer Therapies
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
Prostate Cancer Detection with IsoPSA
Laboratory Tests Post Transplant and for Heart Failure
Lyme Disease Diagnosis and Treatment Mandate
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
Serologic Genetic and Molecular Screening for Colorectal Cancer
Tumor-Informed Circulating Tumor DNA Testing for Cancer Management
Urinary Biomarkers for Cancer Screening, Diagnosis and Surveillance

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Provider Update, May 2023
Provider Update, March 2022
Provider Update, August 2021
Provider Update, April 2020
Provider Update, May 2019

REFERENCES

Not applicable

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