Medical Coverage Policy | Proprietary Laboratory Analyses (PLA)

EFFECTIVE DATE: 10|01|2019
POLICY LAST UPDATED: 02|06|2020

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. Tests with PLA codes must be performed on human specimens and must be requested by the clinical laboratory or the manufacturer that offers the test.

MEDICAL CRITERIA
BlueCHiP for Medicare 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
BlueCHiP for Medicare and Commercial Products
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POLICY STATEMENT
BlueCHiP for Medicare 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.

NOTE: Laboratories are not allowed to obtain clinical authorization on behalf of the ordering physician. In no circumstance shall a physician/provider use a representative of a laboratory or anyone with a relationship to a laboratory, to facilitate any portion of the authorization process, including any element of the preparation of necessary documentation of clinical appropriateness. If a laboratory 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 physician/provider provides a laboratory service that has not been authorized, the service will be denied as the financial liability of the 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

BlueCHiP for Medicare National and Local Coverage Determinations
Expanded Molecular Panel Testing of Cancers to Identify Targeted Therapies
Gene Expression Profiling and Protein Biomarkers for Prostate Cancer Management
Genetic and Protein Biomarkers for the Diagnosis and Cancer Risk Assessment of Prostate Cancer
Laboratory Tests for Heart and Kidney Transplant Rejection
Lyme Disease Diagnosis and Treatment Mandate
Molecular Markers in Fine Needle Aspirates of the Thyroid
Multimarker Serum Testing Related to Ovarian Cancer
Urinary Biomarkers for Cancer Screening, Diagnosis and Surveillance

PUBLISHED

Provider Update, April 2020
Provider Update, May 2019
Provider Update, June 2018
Provider Update, October 2017

REFERENCES

Not applicable