Medical Coverage Policy | Proprietary Laboratory Analyses (PLA) Codes

EFFECTIVE DATE: 09|19|2017
POLICY LAST UPDATED: 09|19|2017

OVERVIEW

Proprietary Laboratory Analyses (PLA) codes are a new addition to the CPT® code set approved by the American Medical Association (AMA) CPT Editorial Panel. They 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.

This policy indicates Proprietary Laboratory Analyses codes that:

- Require/recommend preauthorization via the Clear Coverage online tool
- Are not medically necessary
- Are not covered
- Are covered

MEDICAL CRITERIA

BlueCHiP for Medicare

The Centers for Medicare and Medicaid Services (CMS) defines medical necessity as "Health-care services or supplies needed to diagnose or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine." In addition, Blue Cross & Blue Shield of Rhode Island (BCBSRI), assesses the clinical validity and utility of the test or services being requested to determine if it is reasonable and necessary.

Commercial Products

Generally InterQual Criteria is used to determine medical necessity and is found in the Clear Coverage™ online authorization tool. However, for those policies specifically listed in the Related Policies section of this policy, BCBSRI medical criteria is used.

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

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial products.

If a service that requires prior authorization is performed on an urgent basis, a retrospective authorization must be obtained through the online tool.

If the complexity of a procedure is unknown prior to the service, a retrospective authorization must still be obtained.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Genetic testing is considered medically necessary when the criteria in the online authorization tool has been met.

Genetic testing, using panels of genes is considered not medically necessary. Individual components of a panel may be submitted for review and may be considered medically necessary when criteria is met.

The clinical utility of Next Generation Sequencing Panel tests is uncertain. Therefore, Next Generation Sequencing Panel tests are considered not medically necessary for BlueCHiP for Medicare and are not covered for Commercial products.

> **Note:** For Commercial products, Next Generation Sequencing Panel tests will be not covered as groups renew in 2017. For those groups that have not yet renewed, the service will be not medically necessary, as there is insufficient peer-reviewed literature demonstrating efficacy.
>
> **Exception:** Testing represented by CPT code 81420 is a covered service for BlueCHiP for Medicare and Commercial products.

There are additional genetic testing codes within this policy that 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.

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/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable coverage for surgery.

BACKGROUND

PLA codes are contained in a non-Category I subsection of the Pathology/Laboratory CPT codes. When a specific PLA code is not listed, the test must be reported using either a CPT Category I laboratory code or an administrative Multianalyte Assays with Algorithmic Analyses (MAAAs) code, the later separately listed in Appendix O.

A CPT PLA code and description include the following information:

- Proprietary Name and Clinical Laboratory or Manufacturer

Code Descriptor includes:

- Disease type
- RNA
- Gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin embedded tissue, algorithm reported as a recurrence score

PLA codes, which include many types of tests, have been assigned an alphanumeric structure to expand the code number capacity in the CPT code set and to distinguish these codes from other CPT codes.

Molecular Pathology

Molecular pathology procedures, commonly referred to as genetic testing, are medical laboratory procedures involving the analyses of nucleic acid to detect variants in genes that may be indicative of germline (e.g.,

constitutional disorders) or somatic (e.g., neoplasia) conditions, or to test for histocompatibility antigens (e.g., HLA). Code selection is typically based on the specific gene(s) that is being analyzed. Genes are described using Human Genome Organization (HUGO)-approved gene names.

Next Generation Sequencing
Genomic sequencing procedures (GSPs) and other molecular multianalyte assays are DNA and RNA sequence analysis methods that simultaneously assay multiple genes or genetic regions relevant to a clinical situation. They may target specific combinations of genes or genetic material, or assay the exome or genome. The technology used for genetic sequencing is commonly referred to as next generation sequencing (NGS) or massively parallel sequencing (MPS).

MultiAnalyte Assays
Multianalyte Assays with Algorithmic Analyses 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 (e.g., proteins, polypeptides, lipids, carbohydrates). Algorithmic analysis using the results of these assays, as well as other patient information (if used) is then performed and typically reported as a numeric score(s) or as a probability. MAAAs are typically unique to a single clinical laboratory or manufacturer.

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


PLA Code Grid_10012017.pdf

RELATED POLICIES
Drug Testing
Genetic and Protein Biomarkers for the Diagnosis and Cancer Risk Assessment of Prostate Cancer
Genetic Testing Services
Medical Necessity
Molecular Markers in Fine Needle Aspirates of the Thyroid
Multimarker Serum Testing Related to Ovarian Cancer
Whole Exome and Whole Genome Sequencing for Diagnosis of Genetic Disorders (new policy)

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REFERENCES
Not applicable