Medical Coverage Policy | Multianalyte Assays for Genetic Testing

EFFECTIVE DATE: 01|01|2016
POLICY LAST UPDATED: 12|01|2015

OVERVIEW
The intent of this policy is to document various brand name laboratory genetic tests that are considered not medically necessary for the Commercial population, and may or may not have different coverage determinations for BlueCHiP for Medicare.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
The following services are considered not medically necessary due to insufficient peer-reviewed scientific literature demonstrating efficacy:
CHEMOFX®
81535
81536

The following services are covered for BlueCHiP for Medicare and are considered not medically necessary for Commercial products due to insufficient peer-reviewed scientific literature demonstrating efficacy:
Vectra™ DA
81490

Corus® CAD
81493

Oncotype DX® Colon
81525

VeriStrat®
81538

Cancer TYPE ID
Tissue of Origin
81540

Allomap
81595

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage for laboratory tests or when services are not medically necessary.

BACKGROUND

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 (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.

The format for the code descriptors of MAAAs usually include (in order):

- Disease type (e.g., oncology, autoimmune, tissue rejection)
- Material(s) analyzed (.e.g, DNA, RNA, protein, antibody)
- Number of markers (e.g., number of genes, number of proteins)
- Methodology(ies) (e.g., microarray, real-time [RT]-PCR, in situ hybridization [ISH], enzyme linked immunosorbent assays [ELISA])
- Number of functional domains (if indicated)
- Specimen type (e.g., blood, fresh tissue, formalin-fixed paraffin embedded)
- Algorithm result type (e.g., prognostic, diagnostic)
- Report (e.g., probability index, risk score)

In contrast to genomic sequencing procedures (GSPs) and other molecular multianalyte assays, these assays represent algorithmically combined results of analyses of multiple analytes to obtain a risk score or other value which in itself represents a new and distinct medical property that is of independent medical significance relative to the individual component test results in clinical context in which the assay is performed.

CODING

See Policy Statement section.

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, February 2016

REFERENCES

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