Medical Coverage Policy | Proteogenomic Testing for Patients with Cancer (GPS Cancer Test)

EFFECTIVE DATE: 12|01|2017
POLICY LAST UPDATED: 08|01|2017

OVERVIEW

Proteogenomics refers to the integration of genomic data with proteomic and transcriptomic data to provide a more complete picture of the function of the genome. The current focus of proteogenomics is primarily on the diagnostic, prognostic, and predictive potential of proteogenomics in various cancers. There is one commercially available proteogenomic test, the GPS Cancer test.

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial Products
Not applicable

PRIOR AUTHORIZATION

BlueCHiP for Medicare and Commercial Products
Not applicable

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products
Proteogenomic testing of patients with cancer (including, but not limited to the GPS Cancer test) is considered not medically necessary for all indications due to a lack of peer-reviewed scientific literature.

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 when services are not medically necessary.

BACKGROUND

Proteogenomics is an extremely complex field due to the intricacies of protein architecture and function, the many potential proteomic targets that can be measured, and the numerous testing methods used.

Proteogenomic Testing Methods

Proteogenomic testing involves isolating, separating, and characterizing proteins from biologic samples, followed by correlation with genomic and transcriptomic data. Isolation of proteins is accomplished by trypsin digestion and solubilization. The soluble mix of protein isolates is then separated into individual proteins. This is generally done in multiple stages using high-performance liquid chromatography ion exchange chromatography, 2-dimensional gel electrophoresis, and related methods.

The GPS Cancer test is a commercially available proteogenomic test intended for patients with cancer. The test includes whole-genome sequencing (20,000 genes, 3 billion base pairs), whole transcriptome (RNA) sequencing, and quantitative proteomics by mass spectrometry. The test is intended to inform personalized treatment decisions for cancer, and treatment options are listed when available, although treatment recommendations are not made. Treatment options may include U.S. Food and Drug Administration-approved targeted drugs with potential for clinical benefit, active clinical trials of drugs with potential for clinical benefit, and/or available drugs to which the cancer may be resistant.

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Act. The GPS Cancer™ test (NantHealth, Culver City, CA) is available under the auspices of Clinical Laboratory Improvement Amendments. Laboratories that offer laboratory-developed tests must be licensed by Clinical Laboratory Improvement Amendments for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

For individuals who have cancer and indications for genetic testing who receive proteogenomic testing (GPS Cancer test), the evidence includes cross-sectional studies that correlate results with standard testing and that report comprehensive molecular characterization of various cancers, and cohort studies that use proteogenomic markers to predict outcomes and that follow quantitative levels over time. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and treatment-related mortality and morbidity. There is no published evidence on the analytic validity or clinical utility of the GPS Cancer test. For proteogenomic testing in general, the research is at an early stage. There is a lack of standardization of testing methods and uncertain accuracy for most proteogenomic technologies. A few studies have described assay development and validation for proteogenomic targets and correlation of proteogenomic testing results with standard testing methods. Other studies have used proteogenomic in conjunction with genomic testing to provide a more comprehensive molecular characterization of various cancers. Very few studies have used proteogenomic tumor markers for diagnosis or prognosis, and at least 1 study has reported following quantitative protein levels for surveillance purposes. Further research is needed to standardize and validate proteogenomic testing methods. When standardized and validated testing methods are available, the analytic validity and clinical utility of proteogenomic testing can be adequately evaluated. The evidence is insufficient to determine the effect of the technology on health outcomes. Therefore, the service is considered not medically necessary.

CODING

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There is no established CPT code for the GPS Cancer Test; therefore, it may be reported using an unlisted molecular pathology CPT code.

RELATED POLICIES

Genetic Testing Services

PUBLISHED

Provider Update, October 2017

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