2.04.140 Proteogenomic Testing for Patients With Cancer (GPS Cancer™ Test)

Summary

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.

FDA REGULATORY STATUS

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

POLICY STATEMENT

Proteogenomic testing (see Policy Guidelines section) of patients with cancer (including but not limited to GPS Cancer™ test) is considered investigational for all indications.

POLICY GUIDELINES

Proteogenomic testing involves the integration of proteomic, transcriptomic, and genomic information. Proteogenomic testing can be differentiated from proteomic testing, in that proteomic testing can refer to the measurement of protein products alone, without integration of genomic and transcriptomic information. When protein products alone are tested, this is not considered proteogenomic testing.
2.04.140 Proteogenomic Testing for Patients With Cancer (GPS Cancer™ Test)

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure). Plans may not auto reject services as experimental or investigational. Denials must be made by a physician and plans have the flexibility to give individual consideration and approve an investigational service as medically necessary.

**RATIONALE**

**Summary of Evidence**

For individuals who have cancer and indications for genetic testing who receive proteogenomic testing, 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 validity or 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. A 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 clinical validity and utility of proteogenomic testing can be adequately evaluated. The evidence is insufficient to determine the effect of the technology on health outcomes.

**SUPPLEMENTAL INFORMATION**

**Practice Guidelines and Position Statements**

No guidelines or statements were identified.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.
REFERENCES


POLICY HISTORY

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<tr>
<td>October 2016</td>
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This policy was approved by the FEP Pharmacy and Medical Policy Committee on September 16, 2016 and is effective October 15, 2016.

Signature on File

Deborah M. Smith, MD, MPH