GPS Cancer (NantHealth)

Procedures addressed

The inclusion of any procedure code in this table does not imply that the code is under management or requires prior authorization. Refer to the specific Health Plan's procedure code list for management requirements.

<table>
<thead>
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<th>Procedure addressed by this guideline</th>
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<td>GPS Cancer</td>
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What is GPS Cancer

Definition

NantHealth GPS Cancer™ is a molecular profiling suite used to create personalized treatment plans for cancer patients. The test is for use in patients with solid tumors and utilizes whole DNA genome sequencing of 20,000 genes, whole RNA transcriptome sequencing of over 200,000 transcripts, analysis of proteins for drug sensitivity or resistance, analysis of antigens for monoclonal antibody therapy, quantitative protein analysis, as well as a comparison of tumor DNA to the patient’s normal DNA. These analyses are done to give the health care provider and patient a better understanding of the pathology as well as inform treatment decisions.¹

- Molecular profiling tests used in cancer diagnosis and prognostic applications are generally limited in scope to specific genes or specific proteins. Comprehensive tests that give a full molecular picture of the patient’s tumor may aid in clinical decisions.¹

Test information

- The test suite uses a tissue block sample of the highest carcinoma grade of the patient’s tumor; in some cases, slides can be used. In addition, a sample of the patient’s blood is also sent to NantHealth to compare the patient’s normal DNA to the tumor DNA.²

- The GPS Cancer report includes DNA and RNA mutations/alterations, protein levels, any available therapies (FDA approved), therapies to which the tumor may be resistant, and any clinical trials for which the patient may be eligible. Information from the GPS Cancer report should be interpreted alongside the patient’s medical history, since all potential therapies listed on the report may not be recommended for individuals with certain comorbidities or characteristics.² ³
Guidelines and evidence
• No specific evidence-based U.S. testing guidelines were identified.
• There are no published studies evaluating the analytical and clinical validity and clinical utility of this test. Additional clinical studies are necessary to assess the use of the GPS Cancer test in improving patient health outcomes in patients with cancer.

Criteria
• This test is considered investigational and/or experimental.
  o Investigational and experimental (I&E) molecular and genomic (MolGen) tests refer to assays involving chromosomes, DNA, RNA, or gene products that have insufficient data to determine the net health impact, which typically means there is insufficient data to support that a test accurately assesses the outcome of interest (analytical and clinical validity), significantly improves health outcomes (clinical utility), and/or performs better than an existing standard of care medical management option. Such tests are also not generally accepted as standard of care in the evaluation or management of a particular condition.
  o In the case of MolGen testing, FDA clearance is not a reliable standard given the number of laboratory developed tests that currently fall outside of FDA oversight and FDA clearance often does not assess clinical utility.

References