November 2023

SONIC HEALTHCARE USA

Client Communication

Medicare Local Coverage Determination Policy: CGS

Coverage Policy

L38065 - MolDX: Plasma-Based Genomic Profiling in Solid Tumors

CPT: 81445, 81479

Revision Effective Date: 10/26/2023

Coverage Indications, Limitations, and/or Medical Necessity

This is a limited coverage policy for next-generation sequencing (NGS) assays performed on solid tumor cell-free DNA in plasma, from here on called "liquid biopsies."

Criteria for Coverage

Guardant360® is covered only when **all** of the following conditions are met:

- Patient has been diagnosed with a recurrent, relapsed, refractory, metastatic, or advanced solid tumor that did not originate from the central nervous system. Patients who would meet all of the indications on the FDA label for larotrectinib if they are found to have an NTRK mutation may be considered to have advanced cancer, **and**
- Patient has not previously been tested with the Guardant360® test for the same genetic content. For a patient who has been tested previously using Guardant360® for cancer, that patient may not be tested again unless there is clinical evidence that the cancer has evolved wherein testing would be performed for different genetic content. Specifically, in patients with previously tested cancer, who have evidence of new malignant growth despite response to a prior targeted therapy, that growth may be considered to be sufficiently genetically different to require additional genetic testing, **and**
- Patient is untreated for the primary cancer being tested, or the patient is not responding to treatment (e.g., progression or new lesions on treatment), **and**
- The patient has decided to seek further cancer treatment with the following conditions:
    - The patient is a candidate for further treatment with a drug that is either FDA-approved for that patient's cancer, or has an NCCN 1 or NCCN 2A recommendation for that patient's cancer, **and**
    - The FDA-approved indication or NCCN recommendation is based upon information about the presence or absence of a genetic biomarker tested for in the Guardant360® assay, **and**

SONIC HEALTHCARE USA

Client Communication

- Tissue-based, CGP is infeasible (*e.g.*, quantity not sufficient for tissue-based CGP or invasive biopsy is medically contraindicated) **or** specifically in NSLC Tissue-based CGP has shown no actionable mutations.

If no alteration is detected by Guardant360® or if ctDNA is insufficient/not detected, tissue-based genotyping should be considered.

Other liquid biopsies will be covered for the same indications if they display similar performance in their intended used applications to Guardant360®".

A wide array of cancer treatments have developed ranging from surgery to medications. One of the newer approaches to the medical treatment of cancer has been to use drugs based on genetic features of a malignancy. While many patients will not benefit from genetic testing to select treatment, for those whose cancers have select biomarkers, the treatment of choice often includes therapy targeting that specific biomarker or therapy being avoided because of a biomarker.[1-13]

In spite of the importance of actionable biomarker identification in cancer, research has shown that many patients do not receive genetic testing for the presence of actionable mutations in their cancers, and there are geographic disparities in testing with patients in rural areas and those receiving care at community treatment centers being less likely to receive testing.[14-16] In addition, logistical challenges to testing such as adequate tissue and the availability of any tissue have been identified as barriers to tissue-based genomic testing.[15] Additionally, even among patients whose cancers were genomically profiled at diagnosis and found to have a mutation for which they are receiving targeted treatment, resistance to the initial targeted treatment may emerge. For some patients, the identification of a new mutation, not present in the original tissue sample and found in the blood, may allow the selection of a new targeted life-prolonging therapy.[17]

Client Communication

L38065 - MolDX: Plasma-Based Genomic Profiling in Solid Tumors

CPT: 81445, 81479

The ICD10 codes listed below are the top 40 diagnosis codes Sonic most commonly receives from ordering physicians for this limited-coverage test. Medicare supports provider utilization of all the diagnosis codes listed below, except those notated in bold. If you are providing a diagnosis code that is bolded below, please submit a valid ABN form with the order. To view the complete policy and the full list of medically supported diagnosis codes, please refer to the CMS website for guidance: https://www.cms.gov/medicare-coverage-database/search.aspx

Code	Description
E03.8	**Other specified hypothyroidism**
E29.1	Testicular hypofunction
E72.11	Homocystinuria
E78.2	Mixed Hyperlipidemia
R53.83	Other Fatigue
R79.82	Elevated C-reactive protein (CRP)
R94.4	Abnormal results of kidney function studies