

# November 2023



## Client Communication

# Medicare Local Coverage Determination Policy: CGS

## Coverage Policy

### L38067 - MoIDX: Next-Generation Sequencing for Solid Tumors

CPT: 81445, 81479, 0244U, 0250U

Revision Effective Date: 06/08/2023

#### Coverage Indications, Limitations, and/or Medical Necessity

This policy describes and clarifies coverage for Lab-Developed Tests (LDTs), Food and Drug Administration (FDA)-cleared, and FDA-approved clinical laboratory tests utilizing Next-Generation Sequencing (NGS) in cancer as allowable under the National Coverage Determination (NCD) 90.2, under section D describing Medicare Administrative Contractor (MAC) discretion for coverage. This policy's scope is specific for solid tumor testing, and is exclusive of hematologic malignancies, circulating tumor DNA testing (ctDNA), and other cancer-related uses of NGS, such as germline testing in/for patients with cancer.

#### Criteria for Coverage

All the following must be present for coverage eligibility:

- As per NCD 90.2, this test is reasonable and necessary when:
  - the patient has either:
    - Recurrent cancer
    - Relapsed cancer
    - Refractory cancer
    - Metastatic cancer
    - Advanced cancer (stages III or IV)
  - AND has not been previously tested by the same test for the same genetic content
  - AND is seeking further treatment
- The test has satisfactorily completed a TA by MoIDX® for the stated indications of the test

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Diagnosis codes must be applicable to the patient's symptoms or conditions and must be consistent with the patient's medical record. Sonic Healthcare does not recommend any diagnosis codes and will only submit diagnosis information provided to us by the ordering physician or his/her designated staff.

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- The assay performed includes *at least* the minimum genes and genomic positions required for the identification of clinically relevant FDA-approved therapies with a companion diagnostic biomarker as well as other biomarkers known to be necessary for clinical decision making for its intended use that can be reasonably detected by the test. Because these genes and variants will change as the literature and drug indications evolve, they are listed separately in associated documents such as the MoIDX<sup>®</sup> TA forms.

### **Situations in which Test should not be used or coverage is denied:**

The test in question will be non-covered if:

- It does not fulfill all the criteria set forth in the NCD 90.2 as stated above
- Another CGP test was performed on the same tumor specimen (specimen obtained on the same date of service)
- A TA is not completed satisfactorily by MoIDX<sup>®</sup> for new tests
- For tests that are currently covered but a TA submission has not been made, providers must submit completed TA materials by February 10th, 2020, or coverage will be denied

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

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