November 2023

SONIC HEALTHCARE USA

Client Communication

Medicare Local Coverage Determination Policy: CGS

Coverage Policy

L38584 - MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells

CPT: 81749

Revision Effective Date: 04/27/2023

Coverage Indications, Limitations, and/or Medical Necessity

This is a limited coverage policy for assays that detect biomarkers from circulating tumor cells (CTCs).

Criteria for Coverage

Cancers with established biomarker testing, as recommended by society or national guidelines

Assays that detect biomarkers from CTCs are covered when ALL of the following are met:

- The patient has been diagnosed with cancer
- The specific cancer type has an associated biomarker
- The associated biomarker has already established clinical utility (CU) in the peer-reviewed published literature for the intended cancer type and for the specific indication in the intended patient population
    - The biomarker's CU may include any of the following: it can be used to diagnose, risk-stratify, predict, or monitor response to therapy, as recommended by national or society guidelines (i.e., American Society of Clinical Oncology (ASCO), National Comprehensive Cancer Network (NCCN))
- At least 1 of the following criteria are met AND there is clear documentation of at least 1 of these in the medical record:
    - The patient's cancer has not previously been tested for the specific biomarker, **OR**

  - The patient has newly metastatic cancer, and a metastatic lesion has not been tested for the specific biomarker, **OR**
  - The patient demonstrates signs of clinical, radiological or pathologic disease progression, **OR**
  - There is concern for resistance to treatment based on specific and well-established clinical indications
- Testing for the biomarker can be performed using CTCs
- The CTC-based biomarker test successfully completes a comprehensive Technical Assessment (TA) by Molecular Diagnostic Services Program (MolDX®) that will ensure that Analytical Validity (AV) (including an analytical and clinical validation), Clinical Validity (CV), and CU criteria are met to establish the test as Reasonable and Necessary.
  - The clinical validation has demonstrated performance that is equivalent or superior to tissue-based testing or another already-accepted test for the same biomarker for the same intended use.
  - CV (for new analytes) must be established through studies published in the peer-reviewed literature for the intended use of the test in the intended population.
- Tissue-based testing for the specific biomarker is infeasible (e.g., quantity not sufficient or invasive biopsy is medically contraindicated) **OR** will not provide sufficient information for subsequent medical management (e.g., in cases where human epidermal growth factor receptor 2 (HER2) overexpression is negative in a tissue biopsy but may be positive in the CTCs, due to tumor heterogeneity). There is clear documentation of at least 1 of these reasons for testing in the medical record.
- For a given patient encounter, only 1 test for assessing the biomarker may be performed UNLESS a second test, meeting all the criteria established herein, is reasonable and necessary as an adjunct to the first test.
- Duplicate testing of the same biomarker (*from the same sample type and for the same clinical indication*) using different methodologies is not covered. For example, testing for androgen receptor splice variant 7 (AR-V7) from CTCs by messenger RNA (mRNA) as well as immunohistochemistry (IHC)-based methodologies, for the same clinical indication, will not be covered.

Client Communication

L38584 - MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells

CPT: 81749

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