November 2023

SONIC HEALTHCARE USA

Client Communication

Medicare Local Coverage Determination Policy: CGS

Coverage Policy

L38582 - MolDX: Molecular Testing for Solid Organ Allograft Rejection

CPT: 81479, 81595, 81599, 0118U

Revision Effective Date: 07/27/2023

Coverage Indications, Limitations, and/or Medical Necessity

This Medicare contractor will provide limited coverage for molecular diagnostic tests used in the evaluation and management of patients who have undergone solid organ transplantation. These tests can inform decision making along with standard clinical assessments in their evaluation of organ injury for active rejection (AR).

These tests may be ordered by qualified physicians considering the diagnosis of AR affiliated with a transplant center, helping to rule in or out this condition when assessing the need for or results of a diagnostic biopsy. They should be considered along with other clinical evaluations and results and may be particularly useful in patients with significant contraindications to invasive procedures.

Molecular diagnostic tests that assess a transplanted allograft for rejection status are covered when ALL of the following criteria are met:

- The test must provide information about at least on of the two following clinical status determinations:
    - AR status
    - Cellular or Anibody-mediated rejection (ACR or AMR) status
- The tintended use of the test must be:
    - To assist in the evaluation of adequacy of immunosuppression, wherein a non-invasive or minimally invasive test can be used in lieu of a tissue biopsy in a patient for whom information from a tissue biopsy would be used to make a management decision regarding immunosuppression, OR
    - As a rule-out test for AR in validated populations of patients with clinical suspicion of rejection with a non-invasive or minimally invasive test to make a clinical decision regarding obtaining a biopsy, OR

  - For further evaluation of allograft status for the probability of allograft rejection after a physician-assessed pretest, OR
  - To assess rejection status in patients that have received a biopsy, but the biopsy results are inconclusive or limited by insufficient material.

- The test demonstrates analytical validity (AV), including an analytical and clinical validation for any given measured analytes, and has demonstrated equivalence or superiority for sensitivity or specificity (depending on intended use) of detecting allograft rejection to other already-accepted tests for the same intended use measuring the same or directly comparable analytes.
- Clinical validity (CV) of any analytes (or expression profiles) measured must be established through a study published in the peer-reviewed literature for the intended use of the test in the intended population. The degree of validity must be similar or superior to established and covered tests (see associated coverage Articles). If conducted with concordance to tissue histologic evaluation the Banff Classification for renal allografts or other accepted criteria (if existing) for other organs must be used.
- The test is being used in a patient who is part of the population in which the test was analytically validated and has demonstrated CV.
- For a given patient encounter, only one molecular test for assessing allograft status may be performed UNLESS a second test, meeting all the criteria established herein, is reasonable and necessary as an adjunct to the first test.
- For minimally or non-invasive tests, the benefit to risk profile of the molecular test is considered by the ordering clinician to be more favorable than the benefit to risk profile of a tissue biopsy, or a tissue biopsy cannot be obtained. For example, this may be the case if a biopsy is considered medically contraindicated in a patient.
- The test successfully completes a Technical Assessment that will ensure that AV, CV, and clincal utility criteria are set tin this policy are met to establish the test as REasonable and Necessary.

Covered tests with AV that is significantly below similar services may have coverage rescinded.

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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
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