Regence

Medicare Advantage Policy Manual **Policy ID:** M-LAB51

Laboratory Tests for Organ Transplant Rejection

Published: 10/01/2025

Next Review: 05/2026

Last Review: 09/2026

IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual but they may also be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Laboratory tests have been explored as an alternative or adjunct to biopsy. These laboratory tests are intended to screen for, estimate risk for, detect, and/or to rule out rejection following organ transplantation (allograft).

MEDICARE ADVANTAGE POLICY CRITERIA

Note: The Medicare references in this policy represent the guidance available at publication; please see the Medicare Coverage Database for the latest guidance. This policy includes links to external webpages that are not maintained by the health plan.

National Coverage Determinations (NCDs)

For Medicare Coverage Determinations and Articles, see the Medicare Coverage Database

Heartsbreath Test for Heart Transplant Rejection (NCD 260.10)

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles

For Medicare Coverage Determinations and Articles, see the Medicare Coverage Database

Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:

- ✓ MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38671) *(Companion article A58170, see "Associated Documents" in the LCD)*

Links to prior versions can be found at the bottom of the LCD.

Additional research may be needed to determine coverage for tests or indications not addressed in the LCD and article.

LCDs and Articles for Other Jurisdictions

Note: The health plan is required to use LCDs and articles published by the contractor with jurisdiction over the service area in which the tests are performed.[1,2] See below for contractor guidance in other jurisdictions:

Laboratories in CA and NV:

- ✓ MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38629) and associated article

Laboratories in AL, GA, TN, SC, NC, VA, WV:

- ✓ MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38568) and associated article

Laboratories in IA, KS, MO, NE, IN, MI:

- ✓ MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38680) and associated article

Laboratories in KY, OH:

- ✓ MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38582) and associated article

Additional research may be needed to determine coverage for tests or indications not addressed in these LCDs and articles.

Additional Information

The MolDX program requires that tests complete a technical assessment (TA) for coverage.

The following tests have completed a TA and are listed as "**not covered**":

- Molecular Microscope® MMDx—Heart [0087U] (Kashi Clinical Laboratories)
- Molecular Microscope® MMDx—Kidney [0088U] (Kashi Clinical Laboratories)
- OmniGraf™ (Eurofins-Viracore)

- OmniGraf™ Liver [0576U] (Eurofins-Viracore)

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The following information is required in order to determine medical necessity and potential Medicare coverage for a genetic or molecular diagnostic test. *[See Title XVIII of the Social Security Act, §1833(e), which states no payment may be made unless information necessary to determine payment has been submitted].*

1. The specific name of the test;
2. Name and location of the performing laboratory;
3. Applicable CPT and/or HCPCS code(s);
4. Brief explanation of how the results of the testing are necessary to guide treatment decisions relevant to the member's personal medical history.
5. Medical records relevant to the testing being performed. This includes:
   - o History and physical examinations by the referring physician;
   - o Conventional testing and outcomes; and
   - o Conservative treatment provided, if applicable.

CROSS REFERENCES

1. Genetic and Molecular Diagnostics – Next Generation Sequencing, Genetic Panels, and Biomarker Testing, Genetic Testing, Policy No. 64

REFERENCES

1. Medicare Claims Processing Manual, Chapter 1 - General Billing Requirements, §10.1.5.4 - Independent Laboratories
2. Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §90.4.1 - MAC with Exclusive Jurisdiction over a Medicare Item or Service

CODING

Codes	Number	Description
CPT	0087U	Cardiology (heart transplant), mRNA gene expression profiling by microarray of 1283 genes, transplant biopsy tissue, allograft rejection and injury algorithm reported as a probability score
	0088U	Transplantation medicine (kidney allograft rejection) microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection
	0118U	Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA

0319U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using pretransplant peripheral blood, algorithm reported as a risk score for early acute rejection
0320U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using posttransplant peripheral blood, algorithm reported as a risk score for acute cellular rejection
0493U	Transplantation medicine, quantification of donor-derived cell-free DNA (cfDNA) using nextgeneration sequencing, plasma, reported as percentage of donor derived cell-free DNA
0508U	Transplantation medicine, quantification of donor-derived cell-free DNA using 40 single nucleotide polymorphisms (SNPs), plasma, and urine, initial evaluation reported as percentage of donor-derived cell free DNA with risk for active rejection
0509U	Transplantation medicine, quantification of donor-derived cell-free DNA using 40 single nucleotide polymorphisms (SNPs), plasma, and urine, initial evaluation reported as percentage of donor-derived cell free DNA with risk for active rejection
0540U	Transplantation medicine, quantification of donor derived cell-free DNA using next-generation sequencing analysis of plasma, reported as percentage of donorderived cell-free DNA to determine probability of rejection
0544U	Nephrology (transplant monitoring), 48 variants by digital PCR, using cell-free DNA from plasma donor-derived cell-free DNA, percentage reported as risk for rejection
0575U	Transplantation medicine (liver allograft rejection), miRNA gene expression profiling by RT-PCR of 4 genes (miR-122, miR-885, miR-23a housekeeping, spike-in control), serum, algorithm reported as risk of liver allograft rejection
0576U	Transplantation medicine (liver allograft rejection), quantitative donor-derived cell-free DNA (cfDNA) by whole genome next generation sequencing, plasma and mRNA gene expression profiling by multiplex real-time PCR of 56 genes, whole blood, combined algorithm reported as a rejection risk score
0581U	Transplantation medicine, antibody to non-human leukocyte antigens (nonHLA), blood specimen, flow cytometry, single-antigen bead technology, 39 targets, individual positive antibodies reported
81479	Unlisted molecular pathology procedure
81558	Transplantation medicine (allograft rejection, kidney), mRNA, gene expression profiling by quantitative polymerase chain reaction (qPCR) of 139 genes, utilizing whole blood, algorithm reported as a binary categorization as transplant excellence, which indicates immune quiescence, or not transplant excellence, indicating subclinical rejection

	81595	Cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing subfraction of peripheral blood, algorithm reported as a rejection risk score
	81599	Unlisted multianalyte assay with algorithmic analysis
HCPCS	None	