Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP168

Section: Medical Benefit Policy

Subject: Non-invasive Testing for Organ Transplant Rejection

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Non-invasive Testing for Organ Transplant Rejection

II. Purpose/Objective:

To provide a policy of coverage regarding Non-invasive Testing for Organ Transplant Rejection

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:
The Heartsbreath test assesses heart transplant rejection by measuring the amount of methylated alkanes, a marker of oxidative stress, in the patient's breath. Heart transplant rejection seems to be accompanied by oxidative stress which degrades membrane polyunsaturated fatty acids, creating methylated alkanes that are then excreted in the breath as volatile organic compounds. As per the FDA-approved product labeling, the product is to be used along with endomyocardial biopsy, to diagnose grade 3 heart transplant rejection in patients who have received a heart transplant within the past year.

AlloMap Molecular Expression Testing is a non-invasive, 20-gene expression assay that measures the activity of the immune system with respect to the risk of cardiac allograft rejection. In essence, the testing is thought to detect the absence of rejection in a transplanted heart.

AlloSure is an advanced Next Generation Sequencing (NGS), non-invasive diagnostic test that monitors heart transplant health by quantification of donor-derived cell-free DNA (dd-cfDNA).

Prospera is a non-invasive cf-DNA next-generation sequencing assay that targets over 13,926 single-nucleotide polymorphisms (SNPs) to accurately quantify the fraction of dd-cfDNA in the transplant recipient's blood.

INDICATIONS:

Heart Transplant Testing

AlloMap and AlloSure Heart Transplant Testing

For COMMERCIAL BUSINESS SEGMENT:

AlloMap testing is considered medically necessary when the following criteria are met:

- The member is 15 years of age or older; and
- The member is between 6 months and 5 years post-transplant; and
- The member is otherwise clinically stable and without overt evidence of acute rejection; and
- The member is has not received high dose steroids within the preceding 21 days; and
- The member has not received blood transfusion or hematopoietic growth factor within the preceding 30 days

AlloSure Heart [donor-derived cell-free DNA (dd-cfDNA)] is covered when used in conjunction with AlloMap® to assess the probability of allograft rejection in heart transplant recipients with clinical suspicion of rejection and to inform clinical decision-making about the necessity of a heart biopsy in such patients at least 55 days post-transplant in conjunction with standard clinical assessment.

For MEDICARE AND MEDICAID BUSINESS SEGMENTS:
CMS directives allows AlloMap, an In Vitro Diagnostic Multivariate Index assay (IVDMIA) test service performed in a single laboratory to aid in the identification of heart transplant recipients with stable allograft function who have a low probability of moderate/severe acute cellular rejection (ACR) at the time of testing in conjunction with standard clinical assessment. Palmetto GBA established a formal coverage policy for all Medicare patients. This local carrier determination is applicable nationally.

Renal Transplant Testing

For COMMERCIAL and MEDICARE BUSINESS SEGMENTS:

AlloSure Kidney Transplant

AlloSure Kidney [donor-derived cell-free DNA (dd-cfDNA)] is covered to assess the probability of allograft rejection in kidney transplant recipients with clinical suspicion of rejection and to inform clinical decision-making about the necessity of renal biopsy in such patients at least 2 weeks post-transplant in conjunction with standard clinical assessment.

OmniGraf Kidney Transplant

OmniGraf (combined gene expression profiling and donor-derived cell-free DNA testing) is covered to assess both subclinical acute rejection and clinical acute rejection and to inform clinical decision-making about the necessity of renal biopsy in conjunction with standard clinical assessment.

Prospera Renal Transplant Testing

For MEDICARE BUISNESS SEGMENTS:

The Prospera assay is covered only when the following clinical conditions are met:

- First time renal allograft recipients; and
- Physician-assessed pretest need to further evaluate the member for the probability of active renal allograft rejection

TruGraf Blood Gene Expression Test

The TruGraf Blood Gene Expression Test is covered only when the following clinical conditions are met:

- The member is at least 18 years of age.
- Recipient of a primary or subsequent deceased-donor or living-donor kidney transplantation.
- Stable serum creatinine (current serum creatinine <2.3 mg/dl, <20% increase compared to the average of the previous 3 serum creatinine levels).
- Kidney transplant patients who are more than 90 days post-transplant.
- The member is being managed in a facility that utilizes surveillance biopsies

LUNG TRANSPLANT TESTING

FOR MEDICARE BUSINESS SEGMENT:

AlloSure Lung

Per LCD A58207 MolDX: Molecular Testing for Solid Organ Allograft Rejection which has jurisdiction for PA Medicare beneficieries, AlloSure Lung is a covered service.

EXCLUSIONS:

The Plan does **NOT** provide coverage for Heartsbreath breathing test for heart transplant rejection detection because it is considered **experimental, investigational or unproven.** There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

With the exception of CMS mandated coverage, the Plan does **NOT** provide coverage for the use of peripheral blood measurement of donor-derived cell-free DNA in the management of patients after kidney transplantation (e.g., Prospera), including but not limited to the detection of acute transplant rejection because it is considered **experimental, investigational or unproven.** There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

The Plan does **NOT** provide coverage for the use of peripheral blood measurement of donor-derived cell-free DNA in the management of patients after heart transplantation (e.g., myTAIHEART), including but not limited to the detection of acute transplant rejection because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

Unless otherwise mandated, the Plan does **NOT** provide coverage for the use of peripheral blood measurement of donor-derived cell-free DNA in the management of patients after lung transplantation, including but not limited to the detection of acute transplant rejection or transplant graft dysfunction because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Breath Testing for Heart Transplant Rejection

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

0085T	Breath Test For Heart Transplant Rejection
81479	Unlisted molecular pathology procedure *{AlloSure Heart, AlloSure Kidney, AlloSure Lung, Prospera, TruGraf, OmniGraf}*
81560	Transplantation medicine (allograft rejection, pediatric liver and small bowel) measurement of donor and third party induced CD154=T- cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as rejection risk score
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 *{AlloMap}*
86849	Unlisted immunology procedure *{Allosure Heart, Allosure Kidney, Allosure Lung, MMDX Lung, Kidney Solid Organ Response Test (ksort), nCounter Human Organ Transplant Panel, Prospera, QiSant (also known as Qsant), TruGraf Blood Gene Expression Test}*
0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma *{ MyTAIHeart}*
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 *{ MMDX Heart}*
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 {MMDX Kidney}
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 *{ Viacor TRAC}*
0319U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using pretransplant peripheral blood, algorithm reported as a risk score for early acute rejection (Clarava™)
0320U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using posttransplant peripheral blood, algorithm reported as a risk score for acute cellular rejection (Tuteva™)

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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Local Coverage Determination (LCD): MOLDX: Prospera™ (L38041)

Local Coverage Determination (LCD): MolDX: AlloSure® or Equivalent Cell-Free DNA Testing for Kidney and Heart Allografts (L38255)

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Billing and Coding: MolDX: AlloSure® or Equivalent Cell-Free DNA Testing for Kidney and Heart Allografts MolDx A58387

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MolDX: Molecular Testing for Solid Organ Allograft Rejection A58207

This policy will be revised as necessary and reviewed no less than annually.

Devised: 12/23/05

Revised: 12/07(addition of Allomap), 1/13 (Medicare segment), 12/17 (add indication); 12/19 (add exclusion for cfDNA), 10/20 (Revise title, add Medicare coverage for renal transplant); 10/21(add TruGraf coverage); 5/22 (add OmniGraf coverage); 4/23 (add lung transplant exclusion), 11/23 (add Medicare coverage of AlloSure Lung)

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