Geisinger

# Geisinger Health Plan Policies and Procedure Manual

**Policy: MP236**

**Section: Medical Benefit Policy**

**Subject: Immune Cell Function Assay for Transplant Rejection**

**Applicable line of business:**

| | | | |
|---|---|---|---|
| **Commercial** | **x** | **Medicaid** | **x** |
| **Medicare** | **x** | **ACA** | **x** |
| **CHIP** | **x** | | |

**I. Policy:** Immune Cell Function Assay for Transplant Rejection

**II. Purpose/Objective:**

To provide a policy of coverage regarding Immune Cell Function Assay for 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.

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization

**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:**
Immune cell function assay is intended for use in the detection of cell mediated immunity (CMI) in patients undergoing immunosuppressive therapy post solid organ treatment. The assay is proposed to measure immune suppression and identify patients at risk for infection or rejection. The assay has also been proposed as a means of detecting insured individuals who may be at risk for transplant rejection *prior* to kidney or other solid organ transplantation.

**EXCLUSIONS:**
The Plan does **NOT** provide coverage for the use of immune cell function assay for the measurement of organ transplant rejection following solid organ transplant 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 immune cell function assay for the identification of insured individuals at risk for rejection prior to kidney or any other solid organ transplantation 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.

## SEE ALSO:

**MPA G2098 Immune Cell Function Assay**

**MP168 Non-invasive Testing for Organ Transplant Rejection**

**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: Immune Cell Function Assay for 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.***

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 a rejection risk score **Proprietary test: Pleximmune™**

86352 Cellular function assay involving stimulation (eg, mitogen or antigen) and detection of biomarker (eg, ATP**) note: this code is not covered when used to identify Immuknow™ PleximmuneTM, myTAIHEART or CU Index® testing.PleximmuneTM, CU Index®**

0018M Transplantation medicine (allograft rejection, renal), measurement of donor and third-party-induced CD154+T -cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score Proprietary test: Pleximark



**Associated Key Words: Immune Cell Function Assay, Immuknow™, Pleximmune™, myTAIHEART, CU Index®**

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

**Devised:** 1/2010

**Revised:** 1/18 (added coding); 1/20 (add test reference names), 1/22 (cross-reference MP168), 1/25 (cross-reference Avalon)

**Reviewed:** 1/11, 1/12, 1/13, 1/14, 1/15, 1/16, 1/17, 1/19, 1/21, 1/23, 1/24

**CMS UM Oversight Committee Approval:** 12/23, 5/24, 2/25

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies