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.

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
   Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:
   (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
   (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
   (iii) The service or benefit 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.

**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.

**Associated Key Words:** Immune Cell Function Assay, Immuknow™

**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 PA Medicaid Business segment, this policy applies as written.

**REFERENCES:**
Geisinger TAC Triage Committee. Immune Cell Function Assay August 2010..


Chon WJ, Brennan DC. Investigational methods in the diagnosis of acute renal allograft rejection. UpToDate


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

Devised: 1/2010

Reviewed:

Reviewed: 1/11, 1/12, 1/13, 1/14, 1/15, 1/16, 1/17