COVERAGE:

The Lymphocyte Transformation test (i.e., Lymphocyte Mitogen Response test or the PHE Stimulation test) is considered medically necessary in the diagnosis and management of the following conditions:

- Chronic mucocutaneous candidiasis,
- Congenital or acquired immunodeficiency disorders;
- To study the integrity of lymphokine production,
- Monitor immunosuppressive or immunoenhancing therapy,
- Severe combined immune deficiency,
- To predict allograft compatibility in the transplantation setting,
- DiGeorge anomaly,
- Nezelof syndrome.

Coverage for indications other than those listed above is not considered medically necessary.

Note: The Lymphocyte Transformation test is not covered as a screening test. In addition, it is expected that the results of this test will be used in the management of the patient.

DESCRIPTION:

Lymphocyte proliferation normally occurs early in an immune response. Lymphocyte Transportation Assays test the integrity of the early proliferative response using either nonspecific mitogens or specific antigens to induce blastogenesis. Antigen induced lymphocyte proliferation also correlates with previous exposure and acquisition of cellular immunity.

Lymphocyte Transformation Tests evaluate lymphocyte competence using in vitro tests to assess the ability of the lymphocytes to proliferate and to recognize and respond to antigens. Two types of lymphocyte transformation tests, mitogens assay and antigen assay are discussed in this policy.

The mitogen assay, performed using nonspecific plant lectins, evaluates the mitotic response of T and B lymphocytes to a foreign antigen. In the mitogen assay, a purified culture of lymphocytes from the patient’s blood is incubated with a nonspecific mitogen for 72 hours. The culture is then pulse-labeled with tritiated thymidine and can be measured by a liquid scintillation spectrophotometer in counts per minute, which parallels the rate of mitosis. Lymphocyte responsiveness or the extent of mitosis, is then reported as a stimulation index, determined by dividing the counts per minute of the stimulated culture by the counts per minute of a
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control culture.

The antigen assay uses specific antigens, such as purified protein derivative (PPD), Candida, mumps, tetanus toxoid and streptokinase, to stimulate lymphocyte transformation. After incubation of 4 ½ to 7 days, transformation is measured by the same method used in the mitogen assay.

In the mitogen and antigen assays, a low stimulation index or unresponsiveness indicates a suppressed or defective immune system.

RATIONALE:

Lymphocyte Transformation tests are used for many reasons. Some uses are considered not medically necessary, such as its use as a screening test and to monitor cancer, occupational exposure to dust and other antigens, and other environmental antigens and mitogens. This policy addresses the situations where the use of this test would be considered appropriate.

PRICING:

Usually one service per request is acceptable.

REFERENCES:

• National Jewish Medical & Research Center – Cellular Immunology Tests; Lymphocyte Function Assays; http://www.njc.org/complement/cellular/celr_01.html.

DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.