Medical Policy
Immune Cell Function Assay in Solid Organ Transplantation

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Policy Number: 182
BCBSA Reference Number: 2.04.56

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Immune cell function assay to monitor and predict immune function after solid organ transplantation is considered INVESTIGATIONAL.

Prior Authorization Information
Commercial Members: Managed Care (HMO and POS)
This is NOT a covered service.

Commercial Members: PPO, and Indemnity
This is NOT a covered service.

Medicare Members: HMO Blue℠
This is NOT a covered service.

Medicare Members: PPO Blue℠
This is NOT a covered service.

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.
Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>86352</td>
<td>Cellular function assay involving stimulation (e.g., mitogen or antigen) and detection of biomarker (e.g., ATP)</td>
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ICD-9 Diagnosis Codes

Investigational for all diagnoses.

Description

The "current method of care" for patients who have received a solid organ transplant includes careful monitoring of lifelong immunosuppression and attempts to balance the dual risks of rejection and infection. Because many immunosuppressive agents have narrow therapeutic ranges, and are associated with various toxicities and the potential for drug interactions, the use of therapeutic drug monitoring (TDM) in conjunction with clinical assessment of patients is particularly important. Although levels of immunosuppressive drugs are routinely monitored, they do not always correlate with the degree of immunosuppression, as the pharmacokinetics often differs among individual thus appropriate level of immunosuppressive therapy may vary from person to person.

Immune cell function assays attempt to predict immune function through monitoring cell mediated immunity in immunosuppressed individuals. Some research studies indicate this measurement correlates with increased immune cell response, thus risking solid organ transplantation rejection.

An example of an immune cell function assay to monitor and predict immune function after solid organ transplantation is the ImmuKnow® from Cylex. All immune cell function assays to monitor and predict immune function after solid organ transplantation are considered investigational regardless of the commercial name, the manufacturer or FDA approval status.

Summary

The analytic and clinical validity of immune cell function assays have not been conclusively demonstrated. Further, it remains unclear whether different types of organ transplants or different immunosuppressive regimens affect CD4+ T-cells’ response to phytohemagglutinin (PHA) stimulation variably, or whether cut-off values require adjustment for various clinical scenarios. The clinical utility of immune cell function assays to impact net health outcome in comparison to current methods of care for solid organ transplant recipients has not been evaluated. Therefore, immune cell function assay is considered investigational.

Policy History

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<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>2/2014</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>1/2011</td>
<td>References added</td>
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<tr>
<td>5/1/2010</td>
<td>New Policy</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
References